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PROFESSIONAL

CLINICAL INVESTIGATION PLAN

TITLE: Clinical Investigation of the Safety and Efficacy of an Acetabular Component with a Metal Bearing Surface in Primary Total Hip Replacement.

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REFERENCES

1. INTRODUCTION

It is widely acknowledged that the greatest challenge to the generally very successful procedure of total hip arthroplasty is the incidence of aseptic loosening. The current consensus view appears to be that loosening is largely the result of a biological process of bone resorption secondary to the presence of particulate wear debris (Harris 1994). These particles may result from wear of any of the materials used in the arthroplasty, including metal, PMMA cement or polyethylene. However it has been recognised that the standard articular bearing of metal on ultra high molecular weight polyethylene (UHMWPE) produces a very large number of sub 10 micron UHMWPE particles every year (varying of course with several factors including patient activity and femoral head size). Harris (1994) proposed that for wear-debris induced osteolysis, the "bulk of the evidence supports the concept that it is the submicroscopic polyethylene particles that are the major culprit".

Such observations have led to the search for alternative bearing surfaces in total hip arthroplasty, with the aim of reducing the volume of wear particles. One of the areas explored is that of a metal to metal articulation. The McKee-Farrar method of metal-on-metal arthroplasty was first used in 1951, and good results associated with this have been reported (Bentley & Duthie, 1973; Djurf and Whalstrom, 1986; August et al, 1986). Ring published the results of 1045 of his own design of metal articulating prostheses in 1975, which showed satisfactory results (Ring 1975). Several retrieval studies have shown that wear of metal-on-metal bearings is significantly less than what would be expected from metal on polyethylene prostheses (Walker et al, 1974; McCalden et al, 1995; McKellop et al, 1996; Semlitsch et al, 1989). Many of the clinical failures of the early metal-on-metal designs can be attributed to surgical technique, design, and manufacturing related factors of that era. With the benefit of subsequent technical advances, the preliminary results of more modern designs of cobalt-chrome metal-on-metal prostheses indicate promising long-term performance. Dorr et al (1996) reported on 54 Weber implants at 2-4 years, which have no component loosening or osteolysis. Likewise Wagner & Wagner (1996) reported excellent preliminary results for 67 implants at 4-6 years follow-up.

Despite the lower volumetric wear that is associated with metal-on-metal bearings, one objection that has been raised is the possible toxicity, both local and systemic, of those particles that are produced. Although there may be higher hair, blood and urine concentrations of chromium (Jacobs et al, 1996), and cobalt and chromium (Coleman et al, 1973) in individuals with metal-on-metal implants, more recent post-mortem research (Case et al, 1994) has indicated that the highest levels of disseminated metal particles were found in those subjects with metal-on-polyethylene joint prostheses that were loose and worn. Visuri and Koskenvuo (1991) looked at the incidence of cancer in McKee-Farrar total hip replacements. They concluded that there was no increase in the overall risk of cancer, and incidence of certain cancers was less than expected, although the risk of leukaemias and lymphomas increased. The observed incidence of cancers in this study was noted to be very similar to that in a separate series of standard total hip replacements (Gillespie, 1988). These findings support the theory that changes in cancer incidence are associated with total hip arthroplasty in general, and not specifically with metal-on-metal prostheses.

In summary, metal-on-metal prostheses have been used for many years with promising clinical results. It is expected that the application of modern technology will produce a hip arthroplasty with superior wear characteristics to those of a metal-on-polyethylene prosthesis, therefore leading to improved long-term clinical performance.

2. OBJECTIVES

The investigational device in this study - the ULTIMA® Metal on Metal Acetabular Cup - is an acetabular component with a metal bearing surface, implanted without cement. It meets all of the Essential Requirements under the Medical Devices Directive, with the exception of clinical data to support the design. The principles of the cobalt-chrome metal-on-metal hip articulation have already been proved in long-term studies of similar implants. Therefore this clinical investigation is being conducted to verify that the current device displays the intended short-term performance characteristics related to its' unique design features.

The performance of the acetabular component will be assessed clinically and radiographically during the **short-term** postoperative period (within 6 months of surgery), to determine the efficacy and safety of this investigational implant. During this period the following will constitute a failure of the device: breakage or dissociation of the acetabular component; any change in the position of the component where this cannot be attributed to a patient-specific factor (with the exception of minor degrees of bedding in, where any movement is minimal and non-progressive).

In accordance with contemporary best practice, patients will continue to be followed in the **long-term** to monitor the implant. In the long term, failure of the device will be defined as: breakage or dissociation of the acetabular component; evidence, in the absence of infection, of what in the investigators' opinion constitutes acetabular fixation

failure - namely bone lysis or resorption, cyst formation, alterations in cup position (again with the exception of minor degrees of bedding in, where any movement is minimal and non-progressive); evidence of bone lysis on the femoral side deemed to be secondary to the tracking of articular wear debris.

3. INVESTIGATORS AND STUDY SITES

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Only the above-named investigators, or surgeons working under their direct personal supervision, may perform surgery as part of this study.

4. STUDY SPONSOR AND PERSONNEL

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5. DEVICE DESCRIPTION

A total hip arthroplasty will consist of the investigational acetabular component - the ULTIMA® Metal on Metal Acetabular Cup, ULTIMA® or P.F.C. ® Metal on Metal femoral head and a standard femoral stem. The components are detailed below:

5.1 Acetabular Component

The ULTIMA® Metal on Metal Acetabular Cup is made up of two modular parts - an outer shell and an insert - that are fitted together during surgery. The outer shell is manufactured from wrought titanium alloy (Ti-6Al-4V), a standard orthopaedic implant material. The shell is porous-coated, and designed for implantation without the use of bone cement. The outer shell will be available in the following 11 sizes (where the size is the spherical outer diameter of the shell in mm): 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68. There are three holes in the shell to enable primary fixation using bone screws, if deemed necessary. Standard bone screws manufactured from titanium alloy (Ti-6Al-4V) will be supplied for optional use in conjunction with the acetabular shell. The external geometry, material and surface finish of the outer shell is identical to that of the ZTT™ Acetabular Cup manufactured by Joint Medical Products Corporation of Stamford, USA. The ZTT™ Acetabular Cup has been marketed in the United States of America for approximately three years, where it is used in conjunction with a modular polyethylene liner.

The acetabular insert will fit into the outer shell by means of a taper arrangement - a female taper in the shell and a male taper on the insert. The Morse-style taper is similar to that used for several years in hip prostheses to fit modular femoral heads on to hip stems. The insert is manufactured from Cobalt-chromium alloy (CoCrMo), a standard orthopaedic implant material. It has a spherical bore diameter of 28mm and one size is available which fits all diameters of outer shell. A 10° augmented insert option will also be available for use in patients who require an augmented acetabular cup.

Drawings of the investigational acetabular component, the ULTIMA® Metal on Metal Acetabular Cup, are appended (Appendix 1).

5.2 Femoral Stem

The femoral stems to be implanted in this study are standard products manufactured by Johnson & Johnson Professional, that are currently marketed throughout Europe. The femoral stem to be used will be chosen by the investigator, and will be one of the following:

ULTIMA® Straight Stem	Titanium alloy (Ti-6Al-4V)
ULTIMA® Straight Stem	Cobalt-chromium alloy (CoCrMo)
ULTIMA® LX Cemented Stem	Cobalt-chromium alloy (CoCrMo)
ULTIMA® Collared Stem	Cobalt-chromium alloy (CoCrMo)
ULTIMA® HOWSE™ II Modular Stem	Titanium alloy (Ti-6Al-4V)
ULTIMA® TPS Cemented Stem	Cobalt-chromium alloy (CoCrMo)
P.F.C. ® Cemented Stem	Cobalt-chromium alloy (CoCrMo)
P.F.C.® LX Stem	Cobalt-chromium alloy (CoCrMo)
P.F.C. ® 2 Porous Coated Stem	Titanium alloy (Ti-6Al-4V)

5.3 Femoral Head

The ULTIMA® Metal on Metal femoral heads are the same as the standard ULTIMA® femoral heads except that the tolerance on spherical outside diameter has been tightened. The P.F.C. ® Metal on Metal femoral heads are the same as the standard P.F.C. ® femoral heads except that the tolerance on spherical outside diameter has been tightened and the heads have been modified to increase the amount of spherical bearing surface. The heads are manufactured from Cobalt-chromium alloy (CoCrMo), and have a diameter of 28mm.

For these reasons the femoral heads are also considered to be investigational devices, in addition to the acetabular component.

5.4 Instrumentation

Instrumentation will be supplied for implantation of the investigational acetabular component. Standard instrumentation necessary for implantation of the chosen femoral stem will be used.

6. ETHICS AND LEGAL APPROVAL

6.1 Product Safety

The cobalt-chromium alloy (CoCrMo) from which the implants described in section 5 are manufactured meets standard ASTM F1537, and the titanium alloy (Ti-6Al-4V) meets British Standard BS 7252, Part 3. All implants will be manufactured according to the following standards: BS7251 (Orthopaedic Joint Prostheses), BS7254 (Orthopaedic Implants) and ISO 5839 (Implants for Surgery - Orthopaedic Joint Prostheses - Basic Requirements).

The investigational device has undergone a comprehensive testing programme. A summary of all pre-clinical, mechanical and fatigue testing data is held on file at Johnson & Johnson Professional.

6.2 Ethics Approval

Written approval from the Local Research Ethics Committee will be obtained by the investigator/s before the study commences at each respective trial site.

6.3 Regulatory Approval

This investigation is being conducted to demonstrate conformance of this device with the Essential Requirements of EC Council directive on medical devices 93/42/EEC. Therefore prior notification will be given to the Competent Authority before initiating this investigation, once approval has been obtained from the Local Research Ethics Committee. The investigation will proceed if no objections are placed by the Competent Authority, and it will be conducted according to the European Standard EN 540 - Clinical Investigations of Medical Devices for Human Subjects.

6.4 Patient Consent

Prior to inclusion in the study, written informed consent will be obtained from all patients agreeing to their participation. Patients will be given a 'Patient Information Sheet' (Appendix 2) and will be informed as to the investigational nature of the project, its objectives, potential risks and benefits of the treatment and available alternative. Patients have the right to withdraw from the study at any time without prejudice. The Patient Consent Form is based on the format recommended by the Royal College of Physicians ("Research Involving Patients" Report, January 1990), and a copy is appended (Appendix 3).

7. PATIENT SELECTION

7.1 Inclusion criteria

The inclusion criteria for this study are current indications for standard primary total hip arthroplasty utilising a cementless acetabular component and a cemented femoral component. These include pain, deformity and loss of function which are not responsive to medical treatment.

7.2 Available Alternative Treatments

- a) Osteotomy
- b) Arthrodesis
- c) Girdlestone arthroplasty
- d) Resurfacing hip arthroplasty
- e) Total hip arthroplasty with standard acetabular component utilising a polyethylene bearing surface.

7.3 Exclusion Criteria

- a) Revision total hip arthroplasty
- b) Rheumatoid arthritis
- c) Previous hip joint sepsis
- d) Previous inclusion of the contralateral hip in this study
- e) Recent high dose of corticosteroids
- f) Recent therapeutic radiation
- g) Metabolic disorders of calcified tissue
- h) Charcot arthropathy

- i) Patients who at the time of surgery are judged unsuitable for cementless fixation of the acetabular component
- j) Patients requiring segmental acetabular bone graft, including protrusio.
- k) Previous evidence of sensitivity to cobalt-chromium alloy (CoCrMo) or titanium alloy (Ti-6Al-4V) implants.
- l) Inability to attend for postoperative follow-up visits at the intervals detailed in the protocol
- m) Psychosocial factors that may limit rehabilitation

7.4 Patient Sample

Fifty (50) patients who are candidates for primary total hip arthroplasty will be entered into the study and will receive the investigational device. This number is determined to be sufficient to confirm the short term safety and efficacy of the novel features of the ULTIMA® Metal on Metal Acetabular Cup, without exposing more subjects than necessary to the device which as yet does not have the clinical data required to complete the Essential Requirements of the Medical Device Directive.

Recruitment at each study site will continue until the overall target of 50 patients has been reached. Enrolled subjects must meet the inclusion criteria and meet none of the exclusion criteria. They must understand the nature of the procedure, have read the patient information sheet and document their consent by signing the informed consent form. They may be of either sex.

At Rotherham District General Hospital, randomisation after entry into the study will ensure that the number of patients receiving the investigational device will be matched by patients entered into a control group. Further details of this are given in Appendix 7.

8. STUDY DESIGN

This will be an open, prospective clinical investigation to assess the safety and efficacy of an acetabular component with a metal bearing surface, implanted without cement, in primary total hip arthroplasty. At Rotherham District General Hospital only, patients will take part in a concurrent randomised trial whereby the implant for each patient will be allocated at random at the time of surgery. Further details of this are appended (Appendix 7).

Every patient entered into the study will have their name entered on to the 'Patient Log' (Appendix 4), from which a unique study number will be allocated. The general practitioner of every subject will be informed of their participation in the investigation. Demographic and pertinent medical information from each patient will be recorded on a 'Patient Entry Form' (Appendix 6). A detailed pre-operative clinical assessment will then be made, according to the joint recommendations made by SICOT, AAOS and the Hip Society (Johnston et al, 1990). This information will be recorded on the 'Clinical Assessment Form' (Appendix 6). A standard radiograph will be taken, from which details will be noted on the 'Pre-operative Radiograph Form' (Appendix 6). Subjects will also be asked to complete the 'Patient Questionnaire' (Appendix 6) with details of their pain and level of activity (after Johnston et al, 1990 and Katz et al, 1995). If a patient is due to undergo bilateral hip replacements only one hip will be entered into the study, as observations from bilateral hips cannot be considered completely independent observations. The other hip will be treated outside of the study with an alternative metal-on-polyethylene total hip arthroplasty.

Only investigators listed in section 3 of this protocol, or surgeons working under their direct personal supervision may perform surgery as part of this study. The investigational device - the acetabular component - will be implanted following the recommended surgical technique for that implant. The chosen femoral stem and femoral head (the femoral head also being investigational) will then be implanted according to the recommended surgical technique. A standard and similar surgical technique will be used for all patients. Details of surgery will be recorded on the 'Operative Form' (Appendix 6). After surgery, patients will follow an appropriate rehabilitation programme, the details of which will be recorded on the 'Discharge and Rehabilitation Form' (Appendix 6) together with information on any complications experienced during hospitalisation.

Patients are scheduled to attend for follow-up examinations at the following postoperative intervals: 6 weeks and 6 months, although additional interim visits for specific cases may be undertaken if deemed necessary by the investigator. At each follow-up visit a clinical examination of the operated hip will be carried out, and details recorded on a 'Clinical Assessment Form'. Standard AP and lateral radiographs will also be taken at these intervals, plus any other views as appropriate. From these radiographs observations regarding implant fixation, alignment and bone remodelling will be recorded on the 'Postoperative Radiograph Form' (Appendix 6). Data from the 6-week radiograph will be used as the baseline against which any subsequent changes are measured. Patients will also complete the 'Patient Questionnaire' at each follow-up visit. Any subject failing to appear for examination will be contacted in order to secure his/her return. All patients will be encouraged to attend for further clinical and radiographic follow-up

at appropriate intervals to assess the long-term performance of the device, as is contemporary good practice with all total joint replacements.

At each visit a review of possible complications will be conducted and any should be noted on the 'Complication / Additional Procedure / Withdrawal' form (Appendix 6). If at any other time during the study a complication is noted, a 'Complication / Additional Procedure / Withdrawal' form should be completed with the details. Severe adverse events, or ANY adverse device effects (for definitions see section 13) will be reported to the sponsor, as identified in section 13 of this Clinical Investigation Plan, as soon as possible.

If it is determined that revision surgery is necessary the details should be recorded on a 'Complication / Additional Procedure / Withdrawal' form, identifying the reason for the revision. Such patients will continue to be followed according to the Clinical Investigation Plan until the initial follow-up period is complete.

If for any reason a patient is lost or removed from the study, a 'Complication / Additional Procedure / Withdrawal' form should be completed. This may be the result of loss to follow-up, death, or withdrawal of consent.

9. OBSERVATIONS

All these observations are detailed on the Case Report Forms (Appendix 6).

9.1 Patient Entry Form

Demographics

- Patient Study Number
- Patient Initials
- Sex
- Date of Birth
- Weight (please indicate unit)
- Height (please indicate unit)
- Affected hip
- Duration of symptoms

Review of Exclusion criteria

- None
- Revision total hip arthroplasty
- Rheumatoid arthritis
- Previous hip joint sepsis
- Previous inclusion of the contralateral hip in this study
- Recent high dose of corticosteroids
- Recent therapeutic radiation
- Metabolic disorders of calcified tissue
- Charcot arthropathy
- Patients who at the time of surgery are judged unsuitable for cementless fixation of the acetabular component
- Patients requiring segmental acetabular bone graft (including protrusio)
- Previous evidence of sensitivity to cobalt-chromium alloy or titanium alloy implants.
- Inability to attend for postoperative follow-up visits at the intervals detailed in the protocol
- Psychosocial factors that may limit rehabilitation

Primary diagnosis

- Idiopathic osteoarthritis
- Post-menopausal osteoarthritis
- Post-traumatic osteoarthritis
- Slipped upper femoral epiphysis (SUFE) or Perthes' disease
- Developmental dysplasia of the hip (DDH)
- Other (please detail)

Previous surgery to affected hip

- None
- Internal fixation
- Femoral osteotomy
- Pelvic osteotomy
- Other (please detail)

Previous use of Steroids?

- No
- Yes

Previous use of NSAID?

- No
- Yes

Patient Group Selection

- Group A: Unilateral hip disease, no other limiting condition (Charnley Group A)
- Group B: Bilateral hip disease or some moderately limiting condition, patient compromises activities but is not disabled (Charnley Group B)
- Group C: Multiple joint involvement or some severe limiting condition, patient disabled by pain or function (Charnley Group C)

Level of Disability - Other Joints

- Ipsilateral knee
- Ipsilateral ankle/foot
- Ipsilateral upper extremity
- Contralateral hip
- Contralateral knee
- Contralateral ankle/foot
- Contralateral upper extremity
- Spine

Co-existing medical conditions (and details of any medication taken)

- none
- respiratory disease
- renal disease
- cardiovascular disease
- hepatic disease
- endocrine disease
- neurological disease
- other (details and medication)

Comments

9.2 Clinical Assessment Form

SECTION 1: ASSESSMENT OF PAIN & FUNCTION

Evaluation Date

Patient Study Number

Patient Initials

Affected hip

- left
- right

Degree of Pain

- none

- slight
- mild
- moderate
- marked
- disabled

Occurrence of Pain

- none
- with first steps, then dissipates (start-up pain)
- only after long (30 min) walks
- with all walking
- at all times

Location of Pain

- buttock
- groin
- trochanter
- thigh
- knee
- calf

Occupation (or housewife)

Retired

- No
- Yes

Nursing Home

- No
- Yes

Level of activity

- heavy manual labour - frequently lifts 23-45kg (>50lb.), vigorous sports
- moderate manual labour - lifts <23 kg (< 50lb.), moderate sport (walking or cycling >5km, >3 miles)
- light labour - heavy housecleaning, garden work, assembly line, light sports
(e.g. walking <5km, <3 miles)
- semi-sedentary - white collar job, bench work, light housekeeping
- sedentary - minimum capacity for walking or other activity
- confined to bed or wheelchair

Transport

- able to enter car or public transport
- unable

Putting on shoes and socks

- no difficulty
- slight difficulty
- extreme difficulty
- unable

Sitting

- ordinary chair for one hour
- high chair for half an hour
- unable to sit comfortably in any chair

Sitting to Standing

- can get up from chair without hands/arms
- can get up from chair with hands/arms
- cannot get up independently, need help/sprung chair

Ascending and descending stairs

- normal (foot over foot)
- foot over foot needing banister or assistive device
- two feet on each step
- any other method
- unable

Walking capacity - usual support needed

- None
- One walking stick for long walks only
- One walking stick
- One crutch
- Two walking sticks
- Two crutches
- Walking frame
- Unable to walk

Time walked without support

- Unlimited (greater than 60 minutes)
- 31-60 minutes
- 11-30 minutes
- 2-10 minutes
- Less than 2 minutes or indoors only
- Unable to walk

Time walked with support

- Unlimited (greater than 60 minutes)
- 31-60 minutes
- 11-30 minutes
- 2-10 minutes
- Less than 2 minutes or indoors only
- Unable to walk

Distance walked

- Unlimited
- One mile (1½ km)
- Half and mile (¾ km)
- Indoors only
- Bed and chair

Analogue pain score

SECTION 2: SATISFACTION OF PATIENT (Postoperative only)

Has the operation increased function?

- yes
- no

Has the operation decreased pain?

- yes
- no

Has the operation decreased the need for pain medication?

- yes
- no
- not applicable

Is the patient satisfied with the results?

- yes
- no

What is the status of the hip compared with the last visit?

- better
- same
- worse

SECTION 3: PHYSICAL EXAMINATION BY SURGEON

Limp without support, 20yds, wearing shoes

- None - no limp
- Slight - detected by trained observer
- Moderate - detected by patient
- Severe - markedly alters or slows gait

Range of motion of hip (use + or - signs)

- Fixed flexion (left and right)
- Further flexion to... (left and right)
- Abduction (left and right)
- Fixed adduction (left and right)
- Further adduction to (left and right)
- External rotation, hip in 0 degrees of flexion or maximum extension (left and right)
- Fixed internal rotation, hip in 0 degrees of flexion or maximum extension (left and right)
- Further internal rotation to (left and right)

Trendelenburg Sign

- Left
 - Negative
 - Positive
 - Unable to test
- Right
 - Negative
 - Positive
 - Unable to test

Trendelenburg lurch

- present
- absent

Limb lengths (true leg discrepancy, measured from Anterior Superior Iliac Spine (ASIS) to Medial Malleolus (MM))

- Equal
- Short left (cm)
- Short right (cm)

Complications (Postop. only)

IMPORTANT: at 6 week and 6 month clinic, please REVIEW PATIENT NOTES, and ASK THE PATIENT

- None
- Infection
- Dislocation
- Pulmonary embolism
- Deep Vein Thrombosis - proven
- Deep Vein Thrombosis - unproven
- Myocardial infarction
- Cerebrovascular accident
- Other

(NOTE: All complications must be detailed on a 'COMPLICATION / ADDITIONAL PROCEDURE / WITHDRAWAL FORM')

Medication prescribed since surgery (Postop. only - please detail)

- none
- respiratory
- cardiovascular
- anti-coagulant
- NSAID
- other (please detail)

Comments

9.3 Patient Questionnaire

Your Initials (Please do not write your full name)

Today's date

To be entered by a member of hospital staff: STUDY NUMBER

How much pain do you have in your hip?

- None at all
- Occasional pain that does not prevent activities
- Pain that only affects *strenuous* activities
- Tolerable pain that affects normal activities
- Occasional severe pain with requirement for regular pain-killers
- Severe pain, even in bed

When does your hip pain bother you?

- I have no hip pain
- I only have hip pain with the first few steps, then it goes away
- I only have hip pain after long walks of at least 30 minutes
- I have hip pain whenever I walk
- I have hip pain at all times, even at rest
- Other, please specify

If you have pain related to your hip, where do you feel it?

Please indicate by marking the diagram

On this line, 0 represents no pain and 100 represents agonising pain.

Place a mark on the line to rate the pain from your hip

Choose the phrase that best describes your activity level over the last month

- I frequently lift over 50 lb. (23kg) or play vigorous sports such as singles tennis, or jog
- I lift up to 50 lb. (23kg) or do moderate sports such as walk or bicycle over 3 miles (5 km)
- I do heavy housework such as vacuuming or cleaning floors, garden work, assembly line work, or light exercise such as walking
- I do office work, sedentary work, and light housework
- I do minimal walking or activities around the house or garden
- I am confined to bed or a wheelchair

Are you able to get into a car, or use public transport?

- Yes
- No

Do you have difficulty putting shoes and socks on?

- No difficulty
- Slight difficulty
- Extreme difficulty
- Unable to do

How do you feel when you are sitting down?

- Can sit comfortably for one hour
- Can sit comfortably for half an hour
- Cannot sit comfortably at all

How do you arise from a chair to a standing position?

- I stand up from a chair without using my arms to push off
- I use my arms to push off when standing up from a chair
- I do not stand up from a chair without someone's help

How do you climb stairs?

- Normally, without using the banister or an assistive device (such as a cane), with one foot over the other, placing only one foot on each step
- Using the banister or an assistive device (such as a cane), with one foot over the other, placing only one foot on each step
- Placing both feet on each step
- Other method (please specify)
- I am unable to climb stairs

Do you use any supportive devices

- No
- A single cane for long walks
- A single cane regularly
- A single crutch
- Two canes or crutches sometimes
- Two canes or crutches always
- Walker
- I am unable to walk WITH support

How long can you walk at one time WITHOUT support (WITHOUT a cane, crutch, or walker)?

- Over an hour
- 31 - 60 minutes
- 11 - 30 minutes
- 2 - 10 minutes
- Less than 2 minutes (or indoors only)
- I am unable to walk WITHOUT support

How long can you walk at one time WITH support (WITH a cane, crutch, or walker)?

- Over an hour
- 31 - 60 minutes
- 11 - 30 minutes
- 2 - 10 minutes
- Less than 2 minutes (or indoors only)
- I am unable to walk WITH support

How far can you walk?

- Unlimited
- One mile (1½ km)
- Half a mile (¾ km)
- 2 - 10 minutes
- Indoors only
- Restricted to bed and armchair

PLEASE ANSWER QUESTIONS 18 TO 22 ONLY IF YOU HAVE ALREADY HAD YOUR HIP REPLACEMENT OPERATION

Did your hip replacement increase your function?

- Yes, a lot
- Yes, somewhat
- No my function is the same
- No, my function is worse

Did your hip replacement decrease your pain?

- Yes, completely
- Yes, somewhat
- No
- I had no pain before surgery

Did your hip replacement decrease your need for pain medication?

- Yes
- No
- I did not take pain medication before surgery

How satisfied are you with the results of your hip replacement surgery?

- Very satisfied
- Somewhat satisfied
- Somewhat dissatisfied
- Very dissatisfied

Is your hip better, about the same, or worse compared to when you filled this form out last?

- Better
- Same
- Worse

Please write any further comments you have below:

9.4 Pre-operative Radiograph Form

Patient Study Number

Patient Initials

Date of radiograph

Affected hip

Overall Bone Quality

- Normal
- Porotic
- Sclerotic

Femur

Significant proximal osteopenia

- no
- yes

Acetabulum

Concentric

- no
- yes

Dysplastic

- no
- yes

Superolateral defect

- no
- yes

Subchondral bone plate

- present
- absent
- incomplete

Acetabular cysts

- absent
- present

Minimum depth of acetabular floor (mm)

Comments

9.5 Operative Form

Patient Study Number

Patient Initials

Date of operation

Surgeon

Side

Has patient consent to enter the trial been obtained?

- yes
- no - do not proceed

Rotherham DGH Only - Randomisation Group

- Investigational (metal bearing surface)
- Control (polyethylene bearing surface)

Approach

- Anterolateral
- Lateral
- Posterior
- Other (please detail)

ACETABULUM

Acetabular defects

- None
- Rim
- Central
- Sub-articular
- Global

Visual bone quality after preparation

- Grade I - hard
- Grade II - medium
- Grade III - soft

Medial wall breached?

- No
- Yes

Reaming

- Reamed to size
- Reamed undersize

Acetabular bone graft?

- No
- Yes If yes
 - Type
 - Location

Appearance of acetabular bone before cup insertion

Complete for each segment of the acetabulum (pubic, ischia, iliac - superomedial, iliac - superolateral):

- cortical
- cortico-cancellous
- cancellous

No. of screws used to secure acetabular cup

Location of screws

Any attempt made to seal screw holes in cup before liner insertion?

- No
- Yes (please detail)

FEMUR

Largest broach used in canal preparation

Femoral bone graft?

- No
- Yes If yes
 - Type
 - Location

Femoral cement

- low viscosity - type
- high viscosity - type
- Not applicable

Femoral cement restrictor

- none
- yes - type

Uniform cement mantle thickness visible in proximal femur?

- yes
- no, femoral component transposed
 - anteriorly
 - posteriorly

DETAILS OF PROSTHESES IMPLANTED

Acetabular outer diameter (please circle)

Acetabular outer lot number

Acetabular liner augmentation

- 0 degrees
- 10 degrees

Acetabular liner lot number

Femoral component - type & size

- ULTIMA® Straight Stem (Ti)
- ULTIMA® Straight Stem (CoCr)
- ULTIMA® LX Cemented Stem
- ULTIMA® Collared Stem
- ULTIMA® HOWSE™ II Modular Stem (Ti)
- ULTIMA® TPS Cemented Stem (CoCr)
- P.F.C.® Cemented Stem
- P.F.C.® LX Stem
- P.F.C.® 2 Porous Coated Stem

Femoral Head Neck length

- short
- medium
- long
- extra long
- -3
- 0
- +5
- +10

Intra-operative complications

- none
- perforation of femur
- fracture of femur
- medical complication (please detail)
- other (please detail)

(NOTE: All complications must be detailed on a 'COMPLICATION / ADDITIONAL PROCEDURE / WITHDRAWAL FORM)

Comments

9.6 Rehabilitation and Discharge Form

Patient Study Number

Patient Initials

DISCHARGE INFORMATION

Complications during hospitalisation

- None
- Wound or drain site drainage after 5 days
- Pyrexia
- Dislocation
- Nerve palsy
- Infection
- Pulmonary embolism
- Deep Vein Thrombosis - proven
- Deep Vein Thrombosis - unproven
- Myocardial infarction
- Cerebrovascular accident
- Other (please specify)

(NOTE: All complications must be detailed on a 'COMPLICATION / ADDITIONAL PROCEDURE / WITHDRAWAL FORM)

Date of discharge from hospital

REHABILITATION INFORMATION

Number of days immobilisation

Protected Weight-bearing FROM (date) FOR (days)

Full Weight-bearing FROM (date) FOR (days)

Comments

9.7 Postoperative Radiograph Form

Patient Study Number

Patient Initials

Affected hip

- left
- right

Length of femoral stem component (for scaling purposes, measured from most proximal, lateral point to centre of stem tip - see diagram distance A)

Date of radiograph

Evaluation

- 6 week (baseline)
- 6 month
- other (please detail)

FEMUR

Questions 7-10 to be answered from 6 week radiograph only (for radiographs other than baseline at 6 weeks, please skip to question 11):

Position of stem

- neutral
- valgus
- varus (qualitative only, choose one)

Cement mantle thickness (please complete for each zone 1-7, in mm)

Prosthesis-cement radiolucency

- no
- yes (zones 1-7)

Cement-bone radiolucency

- no
- yes (zones 1-7)

Questions 11-32 to be answered from radiographs other than at 6 weeks (baseline) only:

Varus-Valgus migration of stem (relative to baseline film)

- neutral
- valgus)
- varus) qualitative only: choose one

Subsidence (relative to baseline film)

(must be related to a fixed landmark - tip of lesser trochanter)

- no
- yes: if applicable -
 - within cement (mm)
 - with cement (mm)

Cement fracture (AP)

- no
- yes (zones 1-7)

Stem

- intact
- bent
- fractured

Cement-bone radiolucency (AP) (where present enter max. width in mm)

- no
- yes (zones 1-7)

Resorption of medial part of neck (calcar)

- no
- yes
 - loss of height (mm) (exclusive of rounding)
 - loss of thickness (mm)

Resorption of shaft (AP)

- no
- yes (zones 1-7)

Hypertrophy of shaft (AP)

- no
- yes (zones 1-7)

Endosteal cavitation - lysis (AP)

- no
- yes - width & length in mm (zones 1-7)

Ectopic ossification

- Brooker I (none)
- Brooker II (mild)
- Brooker III (moderate)
- Brooker IV (severe)

ACETABULUM

Evidence of breakage or dissociation of the acetabular component

- no
- yes, please detail

Position of component (relative to teardrop)

- superior (mm)
- medial (mm)

Location of centre of rotation of hip (relative to teardrop)

- superior (mm)
- lateral (mm)

Inclination of cup (abduction)

Version of cup

- retroverted (degrees)
- neutral
- anteverted (degrees)

Prosthesis-bone radiolucency

- no
- yes: maximum width (mm)
 - Zone 1
 - Zone 2
 - Zone 3

Continuous

- no
- yes: maximum width (mm)

Osteolysis

- no
- yes: maximum width (mm)
 - Zone 1
 - Zone 2
 - Zone 3

Continuous

- no
- yes: maximum width (mm)

Hypertrophy

- no
- yes (zones 1-3)

Screws:

- no screws used, skip to next question
- yes screws used, complete a row for each screw position
 - Screw position
 - Radiolucency around screw
 - Broken screw

Porous coating

- intact
- dislodged
- progressive loss

Appearance of acetabular bone graft

- not applicable
- no change
- densified
- absorbed

Comments

9.8 Complication / Additional Procedure / Withdrawal Form

Patient Study Number

Patient Initials

Report date

Description of complication/additional procedure:

Classification of complication

- adverse event (any undesirable clinical occurrence, whether device-related or not)
- adverse device effect (any undesirable device-related clinical occurrence)

(NOTE: ALL ADVERSE DEVICE EFFECTS, AND ANY SEVERE ADVERSE EVENTS MUST BE REPORTED TO THE SPONSOR IMMEDIATELY BY TELEPHONE)

Severity

- mild
- moderate
- severe (resulting in hospitalisation or prolonging hospitalisation of a subject, because of potential disability or danger to life, or because intervention has been necessitated, or if the event is terminal)

Date of onset

Description of complication

Action taken in response

Duration of complication

Outcome

Assessment of relationship of event to implants/surgical procedure

If complication leads to an additional procedure, please detail:

Date of procedure

Description of procedure

Outcome of procedure

Please complete in cases of patient withdrawal

Date of Withdrawal

Reason for Withdrawal

- withdrawal of patient consent
- death
- lost to follow-up
- other, please specify

10. EVALUATION OF DATA

All observations as detailed in section 8 and 9 will be entered on the appropriate case report form for each subject. The investigator must ensure the patient study number is written at the top of each case report form so that individual forms can be identified. In order to maintain patient confidentiality, only the study number as allocated from the central Patient Log and patient initials should be used to identify subjects on study paperwork.

In the **short term** follow-up period (within 6 months of surgery), the following will constitute a failure of the device: breakage or dissociation of the acetabular component; any change in the position of the component where this cannot be attributed to a patient-specific factor (with the exception of minor degrees of bedding in, where any movement is minimal and non-progressive). In the **longer term** (after the first 6 postoperative months), failure of the device will be defined as: breakage or dissociation of the acetabular component; evidence, in the absence of infection, of what in the investigators' opinion constitutes acetabular fixation failure - namely bone lysis or resorption, cyst formation, alterations in cup position (again with the exception of minor degrees of bedding in, where any movement is minimal and non-progressive); evidence of bone lysis on the femoral side deemed to be secondary to the tracking of articular wear debris.

11. STUDY DURATION

Recruitment to this study will continue until the target number of fifty (50) patients have been enrolled. Since long-term follow-up of patients is planned, as per the recommended protocol for total hip arthroplasty, the duration of the study is indefinite.

12. CLINICAL INVESTIGATION PLAN DEVIATIONS

12.1 Loss Or Removal Of Subjects

Every attempt will be made to maintain the evaluation schedule for each subject throughout the study. Any subject who fails to appear for a scheduled examination will be contacted in order to secure attendance. If the subject moves from the area, contact through an orthopaedic surgeon local to the subject's new community will be attempted. Difficulty in securing follow-up is not anticipated since repeated follow-up examinations are considered an essential part of total hip arthroplasty, and only subjects likely and able to return for postoperative follow-up visits will be recruited. If for any reason an investigational device is removed within the initial follow-up period (6 months after surgery), the subject will continue to be followed according to the Clinical Investigation Plan until the end of that period.

Early removal of a living subject from the study will occur only if patient consent is withdrawn.

12.2 Alterations to Clinical Investigation Plan

All investigators will follow this Clinical Investigation Plan for every patient enrolled into the study. Any necessary deviations from this Plan for an individual patient will take place only after prior consultation with the sponsor, and the deviation and reason for it will be recorded on the appropriate Case Report Form. Emergency deviations from the Clinical Investigation Plan (where patient safety may be compromised if the change is not introduced immediately) do not require approval of the sponsor, but the reasons will be recorded on the appropriate Case Report Form and the sponsor notified at the earliest opportunity.

Clinical trial products may only be used by clinical trial investigators, or under their direct personal supervision. The details of each patient who receives an experimental device will be recorded in the Patient Log, and the appropriate case report forms completed. The clinical trial product number (indicated on the label, and prefixed with the letters 'TP') of any device that is discarded must be recorded to maintain traceability of all stock, and such devices will be returned to the sponsor.

On completion of the trial, arrangements will be made with the sponsor for the handling of any unused devices.

15. ANALYSIS OF RESULTS

At the conclusion of the short-term assessment of the investigative device (after 6 months follow-up), a report will be produced by the sponsor and will include a tabular summary of all subjects. Cases will be examined for evidence of acetabular component failure (determined by breakage or dissociation, or component movement - as described in section 10 'Evaluation of Data') and other device-related complications. Clinical observations recorded at follow-up examinations will be summarised and compared to those that are documented for patients who have received a marketed acetabular implant with a polyethylene bearing surface. Data from the Patient Questionnaire will also be examined to assess any changes following surgery, from the patients' perspective.

At suitable intervals during the subsequent long-term follow-up, data on this investigational device, including failure, complication rates and clinical outcome will be compared to that documented for a marketed acetabular implant.

16. STUDY MONITORING

In order to meet the requirements of the EC Council directive on medical devices 93/42/EEC, this Clinical Investigation will be monitored to ensure that it is being conducted according to the European Standard EN 540. To meet this objective the study monitor appointed by the sponsor (identified in section 4.2) will require periodic access to case records, whilst maintaining subject confidentiality. Monitoring visits will be arranged at times mutually convenient for the investigator and monitor.

Any amendments to the Clinical Investigation Plan that are required once the investigation has commenced will be made only after the agreement of the sponsor, and changes will need to be approved by the Ethics Committee at each study site.

13. ADVERSE EVENTS

For the purposes of this investigation, an ADVERSE EVENT is considered to be any undesirable clinical occurrence in a subject whether it is considered device related or not. An ADVERSE DEVICE EFFECT is any undesirable clinical occurrence that is device-related. An adverse event or adverse device effect may be considered severe if it results in hospitalisation or prolonged hospitalisation of a subject, because of potential disability or danger to life, or because an intervention has been necessitated, or if the event is terminal.

All adverse events and adverse device effects occurring during this study will be recorded on the 'Complication / Additional Procedure / Withdrawal Form' (Appendix 6). Information to be reported includes the nature, severity, date of onset, duration, outcome, action taken and relationship to the implants and surgical procedure of any such reaction.

Additionally, due to the investigational nature of the devices, the investigator shall report severe adverse events or any adverse device effects to the sponsor as soon as possible by telephone. These notifications will be followed up by a written report that is submitted to the sponsor no later than seven (7) working days after the investigator first learns of the event. The sponsor will notify the Competent Authority, and other investigators in the study. In the event of a severe adverse device effect, the investigator shall report this to the reviewing Ethics Committee as soon as possible. Reports to the sponsor should be submitted to:

Mr M J Borroff
Research and Development Manager
Johnson & Johnson Professional
Stem Lane
New Milton
Hants
BH25 5NN

Tel No: 01425 624600 or 624610
Fax No: 01425 619923
Home No: 01258 880387

If the Research and Development Manager is unavailable, the Clinical Project Leader should be contacted:

Mrs H Meadows
Clinical Project Leader
Johnson & Johnson Professional
Stem Lane
New Milton
Hants
BH25 5NN

Tel No: 01425 624600 or 624656
Fax No: 01425 619923
Home No: 01962 775392

In the event of device failure (as defined in section 10: Evaluation of Data) during the recruitment phase of the investigation, enrolment of patients will be suspended at all study sites whilst a full investigation of possible causes is undertaken.

14. CONTROL OF INVESTIGATIONAL DEVICES

In any clinical study involving an investigational device, strict control over the clinical trial products is necessary to prevent unauthorised use and to protect the safety of patients who might inadvertently receive an investigational device outside the conditions of the protocol. The following measures are necessary to maintain this control.

Clinical trial products will be labelled to reflect they are for use exclusively for clinical investigation. On delivery of product to the study site, the 'Confirmation of Receipt Form' provided (Appendix 5) must be completed and returned to acknowledge safe receipt of the devices. Clinical trial products should be stored separately from standard products, where they are inaccessible to unauthorised persons. Johnson & Johnson Professional personnel will need periodic access to the inventory of clinical trial products for audit purposes.