

STUDY PROTOCOL

Johnson & Johnson Professional, Inc.
Evaluation of MOM Articulation
with the Ultima MOM Total Hip Systems


Rev B

Protocol 19603
Evaluation of Metal on Metal Articulation with the
ULTIMA[®] MOM Total Hip System - Cemented
(P.F.C.[®] Hip Femoral Stem)

Johnson & Johnson Professional, Inc.
Raynham, MA
Department of Clinical Research
Protocol 19603

July 1998

Investigator's Signature/Date

1. Introduction

Total hip replacement is a procedure with highly predictable, long lasting results. The improvement in patient condition is unquestioned. The procedure will predictably restore function and relieve pain for patients with severe hip damage.

Current efforts in improving total hip replacement are focused on extending the useful life of the implants. Although for most patients, implant survival exceeds the length of time needed (i.e. remaining patient lifetime), failures and revisions do occur. Stem fixation failure associated with bone resorption is a reported cause of total hip joint failure. Foreign particles released from the joint bearing have been implicated in this bone resorption.

A change in the bearing surface would likely change the amount of debris generated by wear of the articulating surfaces of total hip replacement. Replacing the polyethylene surface of the acetabular component with another material has been considered. Improvements in the technology utilized to manufacture high tolerance metal has helped to drive increased interest in a previously used approach to the articulation of total hip replacements. Metal on metal articulation is being considered as an alternative to the types of articulation currently in use.

2. Investigator

3. Objectives

Primary

This study will compare the survival of two total hip systems that incorporate different methods of joint articulation. The experimental system (EXP) incorporates metal on metal (Ultima MOM) articulation. The control system (CTL) incorporates conventional metal on polyethylene articulation. The study hypothesis is that no difference exists in two-year survival of the hip systems. The failure end point will be a revision procedure that involves replacement of any components of the hip system or a determination by the surgeon that such a procedure is indicated.

Patients who have a Harris Hip score of less than 70 with moderate or worse pain at 24-month evaluation will be classified as a failure even if they are not candidates for revision surgery.

Secondary

The clinical performance of the two systems will be compared using a standard hip evaluation scheme. A hip rating scale will be employed. No difference in hip score is anticipated for the duration of the protocol.

4. Test Articles

4.1 Acetabular component

Two different acetabular component systems are utilized. In the experimental group, a metal shell (Ti alloy) is used with a user-inserted metal (CoCr alloy) liner. For the control group, a commercially available system of a similar metal (Ti alloy) shell and user-inserted UHMWPE liner are to be used.

Experimental Product

Reference No.	Description	Size
85-9834	Metal on Metal 3-Hole Shell	48
85-9835	Metal on Metal 3-Hole Shell	50
85-9836	Metal on Metal 3-Hole Shell	52
85-9837	Metal on Metal 3-Hole Shell	54
85-9838	Metal on Metal 3-Hole Shell	56
85-9839	Metal on Metal 3-Hole Shell	58
85-9840	Metal on Metal 3-Hole Shell	60
85-9841	Metal on Metal 3-Hole Shell	62
85-9842	Metal on Metal 3-Hole Shell	64
85-9843	Metal on Metal 3-Hole Shell	66
85-9844	Metal on Metal 3-Hole Shell	68
85-9845	Metal on Metal Standard Insert	28, 0°
85-9846	Metal on Metal Augmented Insert	28, 10°

Control Products (commercially available)

Reference No.	Description	Size
85-1410	P.F.C. Apical Hole Plug	One Size
55-7048	ZTT II 3 Hole Shell (DP)	48
55-7050	ZTT II 3 Hole Shell (DP)	50
55-7052	ZTT II 3 Hole Shell (DP)	52
55-7154	ZTT II 3 Hole Shell (DP)	54
55-7156	ZTT II 3 Hole Shell (DP)	56
55-7158	ZTT II 3 Hole Shell (DP)	58
55-7160	ZTT II 3 Hole Shell (DP)	60
55-7162	ZTT II 3 Hole Shell (DP)	62
55-7164	ZTT II 3 Hole Shell (DP)	64
55-7166	ZTT II 3 Hole Shell (DP)	66
55-7354	ZTT II 3 Hole Shell (DP+6)	66
55-7356	ZTT II 3 Hole Shell (DP+6)	56
55-7358	ZTT II 3 Hole Shell (DP+6)	58
55-7360	ZTT II 3 Hole Shell (DP+6)	60
55-7362	ZTT II 3 Hole Shell (DP+6)	62
55-7364	ZTT II 3 Hole Shell (DP+6)	64
55-7366	ZTT II 3 Hole Shell (DP+6)	66

Reference No.	Description	Size
55-0235	Locking Pins	3.5 mm dia
55-0295	Locking Pins	5 mm dia
52-0826	Poly-Dial Insert, 0°	26
55-1916	Poly-Dial Insert, 10°	26
52-0528	Poly-Dial Insert, 0°	28
52-0628	Poly-Dial Insert, 10°	28
55-7099	ZTT Apical Hole Plug	

4.2 Femoral Components

Femoral components used for control and experimental groups will be standard commercially available P.F.C. Hip system femoral components and sleeves.

4.3 Femoral Heads

Femoral heads used with the control product will be standard commercially available P.F.C. Femoral heads.

Due to the tighter tolerancing requirements for the experimental device articulation, the P.F.C. Femoral Heads for use with the experimental acetabular components have been designated with separate reference codes.

Reference No.	Description	Size
85-9847	MOM Femoral Head (P.F.C.)	28 + 0
85-9848	MOM Femoral Head (P.F.C.)	28 + 5
85-9849	MOM Femoral Head (P.F.C.)	28 + 10

5. Ethics and Legal Approval

This study will be conducted in the United States under a FDA approved Investigational Device Exemption (IDE). The study sponsor, Johnson & Johnson Professional, Inc., will oversee all aspects of the study including compliance with all applicable laws and regulations. Participating investigators will understand and accept their responsibilities prior to study initiation.

6. Patient Selection

6.1 Inclusion Criteria

Indications for use of the MOM Hip System are current indications for hip arthroplasty including a Harris Hip Score of <70 with at least moderate pain. Subjects may not be included unless they meet the inclusion criteria. Subjects must be candidates for a total hip system and fall into one of the following disease states associated with hip arthroplasty:

Osteoarthritis

Post-traumatic arthritis

Avascular necrosis

Limit to Steinberg Grade IV or above

Developmental hip dysplasia

Protrusio acetabula

Slipped capital femoral epiphysis

Crystalline arthropathy

6.2 Criteria for Exclusion

In order to be considered for inclusion into the study, patients must not meet any of the following exclusion criteria. These criteria should be reviewed prior to seeking informed consent from the potential subject.

Previous hip arthroplasty/revision on affected hip

Harris Hip Score ≥ 70 with mild or no pain

Metabolic disorders of calcified tissues; e.g. Paget's disease

History of recent joint sepsis

No active infection of the joint during the previous six months

Charcot neuropathy

Psycho-social disorders that would limit rehabilitation

Patients must have sufficient mental awareness to understand and agree to the required rehabilitation steps

Skeletal immaturity

Rheumatoid or other inflammatory arthritis

Greater than 75 years of age at the time of surgery

Severe osteoporosis

Exclude patients with indication of severe osteoporosis noted on standard x-ray Singh Index = 1

Ipsilateral knee/ankle pain deformity

Severe involvement of other joints of affected limb which would impact rehabilitation

Patients requiring or expecting to require cytotoxic agents or therapeutic radiation

Exclude patients requiring or expected to require over course of protocol

Patients requiring non topical immunosuppressive agents, including corticosteroids

Exclude if requirement exceeds thirty days within three months prior to enrollment or is anticipated during the first six months after surgery. This must be determined at the time of pre-operative examination.

Known requirement for adjunct fixation

Expected need for greater than 10° acetabular liner augmentation

6.3 Available Alternate Treatments

Conservative, non-surgical treatment

A conventional hip joint that does not use cement on the ball (and stem) and may or may not use cement on the socket

Bipolar Hip replacement

Hip fusion

7. Study Design

A maximum of three hundred subjects who meet the inclusion criteria will be entered into this study arm. Please refer to section 16, Statistical Analysis for a discussion of the sample size. They must not meet any of the exclusion criteria, and must understand the experimental nature of the procedure and document their consent to participate by signing the Informed Consent documents.

Subjects entered into the study may be of either sex.

Randomization will be utilized to limit the differences between the two study groups. The surgical technique for implanting the components varies little. The femoral components are commercially available product and are the same for both study groups. The acetabular shell components are very similar in profile and fixation surface. They differ in liner capture mechanism. The acetabular liners represent the major difference between the two systems, that difference being the use of either a metal (EXP) or a polyethylene (CTL) bearing surface.

Each participating subject will be assigned an ID number that will be used throughout the study. If a patient is a candidate for bilateral hip arthroplasty, both hips will receive the same randomization designation based on the initial randomization card drawn.

Each participating subject will be assigned an ID number that will be used throughout the study. If a patient is enrolled for bilateral hip surgery, two different ID numbers will be assigned one for each enrolled side. Study group assigned (EXP or CTL) will be determined by drawing consecutively numbered, sealed envelopes after the patient has been evaluated for entry and exclusion criteria and has completed the informed consent process.

Each patient entered into the study will have demographic data and pertinent past history recorded on the Patient Entry Form (Form 11). All Case Report Forms (CRF) are included in APPENDIX B.

If, at surgery, the investigator determines that a patient is not a suitable candidate for the components allowed by this protocol the patient will not be enrolled in the study. Conventional components will be implanted. Records will be maintained for any patients who are dropped from the study for this reason.

Adjunct acetabular fixation may be used if necessary during surgery. Dome screws used in conjunction with the experimental acetabular components are limited to sizes 6.5mm x 25 and 6.45mm x 45 (Reference Numbers 55-6072→ 55-6076).

The immediate post-operative care is no different from other total hip prosthesis procedures. Patients with a cemented femoral stem are instructed by their surgeon to begin weight bearing as tolerated at one day post-op. This is the same instruction as given to commercially available cemented stem total hip replacement procedures. In addition, daily exercises including isometric and stretching exercises for at least 15 minutes, three times per day as capable are recommended. Subjects will be scheduled for post-operative evaluation at discharge from hospital, at 6 weeks and at 6, 12, and 24 months. Any subject failing to appear for examination dates will be contacted in order to secure return. Some variation of examination dates or some missed examinations will not adversely affect the validity of the study.

Patients who have completed the 24-month evaluation period will be followed at least once every two years with the routine follow-up evaluation for the duration of the study.

Observations regarding pain, function, range of motion and deformity will be assigned a point value and will be used to produce a hip rating score. Routine radiographs taken during each follow-up exam will be examined for lucencies or evidence of component loosening. At each scheduled visit, a review of complications/adverse events (device-related or not) will be conducted and will be recorded on case report forms and reported.

If it is determined that revision surgery is required, a Re-Operation Form (Form 61) will be completed identifying the reason for the procedure. Any individual who undergoes revision procedure will be followed for the duration of the study.

8. Observations

Note: All CRF's will include a patient ID field and an optional patient initials field. The affected side is also included on each CRF. Each form contains a region to enter comments and a signature line.

Patient Entry (Form 11)

<p>Bilateral Study Patient</p> <ol style="list-style-type: none"> 1. No 2. Yes 	<p>Has subject previously been enrolled into this clinical trial for the other hip? Please enter the ID assigned to the patient for the other hip</p>
<p>Demographics</p> <ol style="list-style-type: none"> 1. Birth Date 2. Gender 3. Height and height unit 4. Weight and weight unit 	
<p>Duration of Symptoms, in years</p>	<p>Time in years that symptoms have occurred more than 2 weeks per month rounded by > 6 go to next year. Best estimate</p>
<p>Patient Aware of any Allergies</p> <ol style="list-style-type: none"> 1. None 2. To metals 3. To drugs 	
<p>Review of Exclusion Criteria</p> <p>Patient must not meet any of these criteria as a condition of enrollment</p> <ol style="list-style-type: none"> 1. None 2. Previous hip arthroplasty/revision 3. HHS \geq 70 with mild/no pain 4. Calcified tissue disorders 5. History of recent joint sepsis 6. Charcot neuropathy 7. Psycho-social disorders that would limit rehabilitation 8. Skeletal immaturity 9. Rheumatoid or other inflammatory arthritis 10. Greater than 75 years of age 11. Severe Osteoporosis 12. Severe pain or deformity of knee or ankle on the affected side 13. Currently uses or requires cytotoxic agents or therapeutic radiation 14. Use of Immunosuppressants (includes corticosteroids) 15. Known requirement for adjunct acetabular fixation 	<p>Any type of previous hip arthroplasty on this side. Harris Hip Score</p> <p>No active infection of the joint during the previous 6 mos.</p> <p>Radiographic observation of thinning. Singh Index Grade = 1</p> <p>At the time of enrollment or use is anticipated within the study period</p> <p>Use exceeds 30 days and occurs within 3mo. of enrollment or is anticipated within 6 mo. of surgery This must be determined at the time of pre-operative examination</p>

PRE-OPERATIVE OBSERVATIONS

Observations noted below will be made for each patient enrolled into the study. Observations recorded in the four categories: pain, function, range of motion and absence of deformity will be assigned a point score modified from Harris, (Journal of Bone and Joint Surgery, Vol. 51-A, p. 737).

The point values, where applicable, are included in the observation description. Categories have been modified to comply with joint recommendation of the Hip Society, SICOT and the American Academy of Orthopedic Surgeons as described in the Journal of Bone and Joint Surgery, Volume 72-A, No. 2.

Pre-Operative Observations (Form 12)

Date of Evaluation	
Pain Information Pain 1. None 2. Slight 3. Mild 4. Moderate 5. Marked 6. Totally Disabled	Patient comment regarding level of pain in operated hip (44 pts) No pain or ignored (38) Occurs occasionally; no compromise in daily activities (30) No limitation of ordinary activity, rarely moderate pain with unusual activity. May take aspirin (20) Tolerate but requires concession. Some limitation of ordinary activity or work. May require occasional pain medicine stronger than aspirin (10) Serious limitations of activities (0) Crippled by pain, bedridden
When Does Pain Occur 1. Never 2. With first steps, then dissipates 3. Only after long (30 min) walks 4. Both with first steps and after long walks 5. With all walking 6. At all times	This response is a combination of 2 and 3 But not during rest

Pre-Operative Observations (cont.) (Form 12)

<p>Pain Location If multiple location, describe location where pain most severe 1. None 2. Groin 3. Buttock 4. Hip Joint 5. Thigh</p>	<p>Most severe</p>
<p>Function</p>	<p>As noted on operated side</p>
<p>Gait Limp 1. None 2. Slight 3. Moderate 4. Severe</p>	<p>(11 pts) 100% weight bearing on affected side (8) 66-99% weight bearing on affected side (5) 33-65% weight bearing on affected side (0) 0-33% weight bearing on affected side</p>
<p>Support - required to walk comfortably and smoothly 1. None 2. Cane, long walks 3. Cane, mostly 4. One crutch 5. Two canes 6. Two crutches 7. Walker 8. Not walking</p>	<p>(11 pts) (7) (5) (3) (2) (0) (0) must specify reason (Harris, 1968) ability to walk on a regular basis</p>
<p>Distance Walked 1. Unlimited 2. Six blocks 3. Two or three blocks 4. Indoors only 5. Bed and chair 6. Unable</p>	<p>(11 pts) (8) (5) (2) (0) (0)</p>

Pre-Operative Observations (cont.) (Form 12)

Activities	
Stairs Ascending and Descending 1. Normally 2. Able, rail 3. Any Manner 4. Unable	(4 pts) foot over foot, does not require railing (2) foot or foot, must use railing (1) stairs in any manner (0)
Enters car or public transportation 1. Yes 2. No	Evaluate ability to get into car or public transportation (1 pt) (0)
Sitting 1. Comfortable 2. Limited 3. Unable	(5 pts) in normal chair for one hour (3) one half hour on a high chair (0)
Sitting to Standing 1. No Assistance 2. With upper extremity 3. Unable	Able to raise from chair without use of upper extremity Able to rise from chair using arms Requires assistance of another
Shoes and Socks 1. With ease 2. With difficulty 3. Unable	(4 pts) puts on socks and ties shoes with ease (2) puts on socks and ties shoes with difficulty without assistance (0)

Pre-Operative Observations (cont.) (Form 12)

Range of Motion	Range	X Index =	Maximum Value
1. Flexion	0-45°	1.0	45
	45-90°	0.6	27
	90-110°	0.3	6
	110-130°	0.0	0
2. Abduction (in extension)	0-15°	0.8	12
	15-20°	0.3	1.5
	20-45°	0.0	0
3. External Rotation (in extension)	0-15°	0.4	6
	>15°	0	0
4. Internal Rotation (in extension)	Any	0	0
5. Adduction (in extension)	0-15°	0.2	3
	Over 15°	0	0
Total possible motion point value X overall factor 0.5 =			100.5
Absence of Deformity 1. Fixed flexion contracture 2. Fixed adduction 3. Fixed Internal rotation		Requires all four (for a total of 4 pts.) less than 30° less than 10° less than 10° measured in extension	
Limb length discrepancy 1. None 2. Shorter 3. Longer		less than 3.2 cm	
Summary Scoring System 1. Pain 2. Function 3. Deformity 4. Range of Motion Total		(44 pts) (47) (4) (5)	
Trendelenburg Sign 1. Negative 2. Positive 3. Unable to test		Affected side	

Pre-Operative Observations (cont.) (Form 12)

<p>Medication Indicate if any of the listed medications are taken routinely</p> <ol style="list-style-type: none">1. None2. ASA3. NSAIDS4. Oral steriods5. Narcotic analgesics	<p>≥ 4 times per week Please indicate if medication is taken for: Affected hip Other problem Both</p>
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Pre-Operative Radiographs (Form 15)

Radiographic Observations - AP and Lateral View

Date of radiograph	
Femoral deformity Each is rated a No or Yes 1. Head 2. Neck 3. Shaft	
Femoral intramedullary flare 1. champagne glass 2. proportional 3. stovepipe	A B C
Joint space	mm
Osteoporosis 1. Type I 2. Type II Grade of osteoporosis	Postmenopausal (within 15-20 yrs. of menopause) affects mostly trabecular bone Senile osteoporosis (men and women over age 70) affects cortical and trabecular bone equally Using the Singh Grade 2,3,4,5,6; Singh Grade 1 see exclusion criteria
Osteophytes 1. In joint space 2. At joint margin	Mark all that apply
Acetabular Description 1. Normal 2. Enlarged 3. Medial wall defect 4. Anterior rim defect 5. Posterior rim defect 6. Dome defect	Mark all that apply
Acetabular Dysplasia 1. No 2. Yes, mild 3. Moderate 4. Severe 5. Pseudo-acetabulum	
Acetabular Protrusio 1. No 2. Yes	mm
Ectopic Ossification 1. None 2. Brooker I 3. Brooker II 4. Brooker III 5. Brooker IV	

Operative Observations (Form 21)

Date of Procedure	
Operation time, skin to skin	
Surgical Approach 1. Posterior lateral 2. Posterior medial 3. Watson-Jones/anterior lateral 4. Anterior medial 5. Direct lateral 6. Other	Please describe
Components Implanted For each unit, provide the reference number and the lot number 1. Femoral Stem 2. Femoral Head 3. Femoral Sleeve 4. Acetabular shell 5. Acetabular liner	
Locking of Polyliner 1. 3.5 Locking Pins (55-0235) 2. 5.0mm Locking Pin (55-0295) 3. Peripheral Screws Placed	Control device only Enter reference number
Dome Screws Placed 0 None 1 One 2 Two 3 Three	
Trochanter 1. On 2. Off 3. Slide	

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Operative Observations (cont.) (Form 21)

Acetabulum Reamed	
1. No 2. Yes	Last reamer used (mm)
Depth of subchondral plate 1. Intact 2. Reamed through	
Acetabular/Femur bone graft placed 1. No 2. Yes, morcellated bone 3. Yes, bulk autograft 4. Yes, bulk allograft	
Subchondral Bone Drilled/Acetabular/Femur 1. No 2. Yes	
Acetabular Cyst(s) 1. None 2. Present, no intervention 3. Present, curetted 4. Present, curetted and grafted	
Bone Strength Acetabular/Femoral 1. Normal/Sclerotic 2. Cystic 3. Porotic	

Follow-Up Observations (Form 41)

This form is completed at each follow-up interval and if the patient appears for an extra visit due to a problem with the affected hip joint. It contains the same information as the Pre-Operative Observation Form (Form 12) with the addition of an indication of follow up examination visit and a check for complications.

Protocol visit identification	Evaluation
Complications	
NOTE: All complications should be reported on Form 51 1. None 2. Yes	All information reported on Complication Form 51 Yes, please describe

Follow-Up Radiographs Femoral Component (Form 46)

Form is completed at all Post-operative visits beginning with the 6-week visit.

Protocol visit identification	Evaluation
Date of radiography	
Stem type	Cemented/cementless
Migration of Stem 1. None 2. Migration into valgus 3. Migration into varus	
Subsidence Related to fixed landmarks on femur; proximal tip of greater trochanter and mid-point of lesser trochanter 1. No 2. Yes	Provide distance in mm
Ectopic Ossification 1. None 2. Brooker I 3. Brooker II 4. Brooker III 5. Brooker IV	Islands of bone within soft tissue Bone spur at end of pelvis or femoral head leaving 1 cm Islands of bone within soft tissue bone spur at end of pelvis or femoral head leaving <1 cm Ankylosis
Resorption of Medial Femoral Neck (calcar) 1. No 2. Yes	Loss of height and loss of thickness in mm
Radiolucency 1. None 2. Yes	Enter AP or Lateral Enter lucency: prosthesis-bone prosthesis-cement cement-bone resorption hypertrophy Enter thickness in mm for zones 1 through 7
Loss in bone density 1. No 2. Yes	Enter AP If yes, Patchy loss Uniform loss Increased Trabecular bone Endosteal cavitation lysis Enter thickness in mm for zones 1 through 7

Follow-Up Radiographs of Acetabular Component (Form 45)

Form is completed at all post-operative visits beginning with the 6-week visit.

Protocol visit identification	Evaluation
Date of radiography	
Inclination of cup (abduction) in degrees Version of Cup 1. Neutral 2. Retroverted 3. Anteverted 4. Not measurable	Provide degrees
Acetabular Radiolucency 1. No 2. Yes	Enter AP Enter lucency in mm for Zones 1 through 3
Location of center of rotation of hip relative to teardrop, in mm 1. Superior 2. Medial	
Appearance of acetabular bone graft 1. None 2. No change 3. Densified 4. Absorbed	No graft present since initial postoperative exam
Acetabular Radiographic Complications Report any Radiographic Complications Noted at this Follow-up Visit 1. No 2. Yes	If yes, provide details on Complications Form 51

Re-operation Observations (Form 61)

In the event of reoperation surgery, the following observations will be recorded

<p>Date of reoperation procedure</p> <p>Reason for surgery procedure</p> <ol style="list-style-type: none"> 1. Dislocation 2. Fracture 3. Infection 4. Implant failure 5. Indication component loosening 6. Other 	<p>Mark all that apply</p> <p>Please describe</p>
<p>Components implanted</p> <p>Non-JJPI Product</p> <ol style="list-style-type: none"> 1. Femoral stem 2. Femoral head 3. Femoral sleeve 4. Acetabular shell 5. Acetabular liner 	<p>For each unit, provide the reference number and the lot number</p> <p>Mark if components implanted are not JJPI devices</p>
<p>Surgeon comments</p>	<p>Describe condition of explant and/or revision</p>

Complication Observations (Form 51)

In the event of any severe/unanticipated complications, sponsor must be immediately notified. Observations will be recorded.

Report date	
Date of complication onset	
Date of complication resolution	
Was the complication confirmed by radiograph 1. Yes 2. No	
Date of radiograph	
Complication 1. Dislocation 2. Fracture of acetabulum 3. Fracture of femur 4. Implant loosening 5. Implant failure 6. Indication of debris 7. Superficial wound infection 8. Deep joint infection 9. Other	Mark one only. Use a separate Form 51 for each complication Please describe
Severity of complication 1. Mild 2. Moderate 3. Severe	
Affected components	All that apply
Intervention 1. None 2. Medical 3. Other conservative therapy 4. Surgical	Enter date of intervention and specify type If surgical intervention is required, please complete Reoperation Form 61

Withdrawal/Termination Report (Form 71)

This form is used to report any patient who leaves the study by request or because of loss to follow-up.

Effective Date	
Reason for Withdrawal	
1. Patient request	
2. Patient refused to return	
3. Lost contact	
4. Death	Date
5. Other	Please explain

9. Adverse Reactions

All adverse reactions occurring during the study, including the nature, severity and relation to the test article of any such reaction, will be reported on the appropriate case report form. Additionally, unusually severe adverse reactions shall be reported immediately by telephone to the sponsor. The sponsor will work with the investigator to determine if the reaction is an unanticipated adverse reaction.

A report of any unanticipated adverse reactions shall be submitted to the sponsor and the reviewing Institutional Review Board as soon as possible, but no later than ten (10) working days after the investigator first learns of the effect. Reports should be submitted to the Clinical Research Associate.

Wini T. Dillon
Manager of Clinical Research
Johnson & Johnson Orthopedics, Inc.
325 Paramount Drive
Raynham, MA 02767
Office: (508) 828-3415
Home: (781) 575-9467

Cyrus Guidry
Director, Clinical Research
Johnson & Johnson Orthopedics, Inc.
Raynham, MA 02767
Office: (508) 880-8124
Home: (617) 763-6311

10. Evaluation of Data

All experimental observations will be entered on the appropriate case report form for each subject. A separate CRF is provided for use if any subject undergoes a second operative procedure on the replaced hip (Case Report Form #61).

All data are forwarded to the sponsor for data entry and analysis. Any complications reported are assessed as received. On a periodic basis, data will be reviewed for any indication of trends.

11. Study Duration

It is anticipated that the study will be completed within four years, assuming adequate patient entry. The sponsor reserves the right to discontinue the study with suitable notice to the investigator in writing.

12. Loss or Removal of Subject

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 exam will be contacted by mail or telephone in order to secure attendance. If the subject moves from the area, contact through an orthopedic surgeon local to the subject's new community will be attempted. Difficulty in securing follow-up is not anticipated as repeated follow-up examinations are considered an essential component of any total joint arthroplasty procedure.

13. Clinical Supplies and Monitoring

The investigator will maintain an inventory of all experimental supplies under his supervision as well as a record of the quantity and lot number(s) of all test articles.

At the conclusion of the study the investigator shall return to the sponsor any remaining supply of the test material or otherwise dispose of the device as the sponsor directs.

The investigator will permit a representative of the sponsor's monitoring team to review all case report forms and study related adjunctive data at regular intervals throughout the study. These reviews are for the purposes of verifying the adherence to the protocol and the completeness and exactness of the data being entered as required by Federal Regulations.

14. Patient Consent

Written informed consent will be obtained from all patients or responsible representatives, who will be properly informed as to the reason for this study, potential risks and benefits of the treatment applied and alternatives to the test treatment.

15. Alterations of Protocol

No changes of the protocol with the exception of those of emergency nature will be made without written consent from the sponsor and by mutual agreement between the investigator and sponsor. All changes will be recorded by the investigator and submitted to the sponsor, and the investigator's governing IRB.

The sponsor will obtain written approval for changes in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects from FDA, prior to initiating such changes.

16. Statistical Analysis

The study is designed as a randomized controlled clinical trial. Both arms will follow the same protocol. Each arm will include a maximum of 300 patients (150 in each study group). This sample size will be able to determine whether the treatment group is equivalent to the control group. Equivalence is defined as a difference between two-year survival of less than .08 (control group minus treatment group).

Estimated sample size requirements were determined based upon the following assumptions:

Current (control) success rate of	0.98
Projected experimental rate of	0.98
Equivalency (Control - Experimental)	<.08
Test type	X ² Test of Equivalence
Type I Error	$\alpha = .05$
Type II Error	$\beta = .05$

Not more than 20% of patients failing to complete the 2 year protocol

Based upon these assumptions, a sample size of 125 will yield a test with 95% power to determine whether the two groups are equivalent.

A baseline analysis of the experimental and control populations will be performed to determine whether the random assignment resulted in equivalent experimental and control groups. Tabulations of Age Group, Primary Diagnosis, Coexistent Disease and Status of Other Joints reported on pre-operative data collection forms will be compiled for comparison.

An analysis of safety and effectiveness data comparing experimental and control groups will be performed. The following variables will be included:

- a) Implant Survival
- b) Hip Score
- c) Pain Rating

Hip implants that undergo a revision surgery that involves the recommended replacement of any hip component will be classified as a failure. In addition, any

patient with a pain rating of moderate or worse in the affected hip, at 24 months will be considered a failure. Success is defined as any 24-month post-operative Harris Hip Score that is ≥ 70 and is accompanied by mild to no pain. Survival curves will be calculated for the experimental and control groups. These curves will be compared using the Log-Rank Test. Hip Scores and Pain Ratings will be analyzed simultaneously with a multiple analysis of variance (MANOVA) to identify any differences between experimental and control groups. This overall test will assure that the α of 0.05 will apply to both dependent variables simultaneously (family α 0.05). If a statistically significant difference is observed then a Student's t- Test for independent means will be performed on each dependent variable.

These analyses will be performed on all data collected at the two-year post-operative examination. A similar analysis will be performed on the last available follow-up data. Subjects with only six-month data will be excluded from this analysis because these data are considered to be within the initial healing and adjustment period and are not representative of the long term result.

Baseline analyses will be performed to compare pre-operative characteristics (e.g. Age, Primary Diagnosis, Coexistent Disease and Status of Other Joints) of those lost to follow-up with those in the final cohort in order to assess bias due subjects lost to follow-up. Study center effects will be explored by comparing the major outcomes across study centers.

A Logistic Regression analysis will be performed to determine whether there are any associations between pre-operative characteristics and post-operative survival. Hip Score and Pain Rating will be evaluated in a similar manner using stepwise multiple regression.

When actuarial analysis indicates that there are 100 unilateral patients in each group with 24-month data available, analysis will be completed on these patients and enrollment will be terminated.

17. Analysis of Protocol

Data collected in four categories; pain, function, absence of deformity and range of motion, will be applied to the rating scale proposed by Harris (J. of Bone and Joint Surgery, Vol 51-A: 737, June 3, 1969). The use of a rating system provides a reproducible and reasonable objective system for combining important variables into a single figure.

Protocol 19602
Evaluation of Metal on Metal Articulation with the
ULTIMA[®] MOM Total Hip System - Cementless
(S-ROM[®] Hip Femoral Stem)

Johnson & Johnson Professional, Inc.
Raynham, MA
Department of Clinical Research
Protocol 19602

July 1998

Investigator's Signature/Date

1. Introduction

Total hip replacement is a procedure with highly predictable, long lasting results. The improvement in patient condition is unquestioned. The procedure will predictably restore function and relieve pain for patients with severe hip damage.

Current efforts in improving total hip replacement are focused on extending the useful life of the implants. Although for most patients, implant survival exceeds the length of time needed (i.e. remaining patient lifetime), failures and revisions do occur. Stem fixation failure associated with bone resorption is a reported cause of total hip joint failure. Foreign particles released from the joint bearing have been implicated in this bone resorption.

A change in the bearing surface would likely change the amount of debris generated by wear of the articulating surfaces of total hip replacement. Replacing the polyethylene surface of the acetabular component with another material has been considered. Improvements in the technology utilized to manufacture high tolerance metal has helped to drive increased interest in a previously used approach to the articulation of total hip replacements. Metal on metal articulation is being considered as an alternative to the types of articulation currently in use.

2. Investigator

(Investigator)

3. Objectives

Primary

This study will compare the survival of two total hip systems that incorporate different methods of joint articulation. The experimental system (EXP) incorporates metal on metal (Ultima MOM) articulation. The control system (CTL) incorporates conventional metal on polyethylene articulation. The study hypothesis is that no difference exists in two-year survival of the hip systems. The failure end point will be a revision procedure that involves replacement of any components of the hip system or a determination by the surgeon that such a procedure is indicated.

Patients who have a Harris Hip score of less than 70 with moderate or worse pain at 24-month evaluation will be classified as a failure even if they are not candidates for revision surgery.

Secondary

The clinical performance of the two systems will be compared using a standard hip evaluation scheme. A hip rating scale will be employed. No difference in hip score is anticipated for the duration of the protocol.

4. Test Articles

4.1 Acetabular component

Two different acetabular component systems are utilized. In the experimental group, a metal shell (Ti alloy) is used with a user-inserted metal (CoCr alloy) liner. For the control group, a commercially available system of a similar metal (Ti alloy) shell and user-inserted UHMWPE liner are to be used.

Experimental Product

Reference No.	Description	Size
85-9834	Metal on Metal 3-Hole Shell	48
85-9835	Metal on Metal 3-Hole Shell	50
85-9836	Metal on Metal 3-Hole Shell	52
85-9837	Metal on Metal 3-Hole Shell	54
85-9838	Metal on Metal 3-Hole Shell	56
85-9839	Metal on Metal 3-Hole Shell	58
85-9840	Metal on Metal 3-Hole Shell	60
85-9841	Metal on Metal 3-Hole Shell	62
85-9842	Metal on Metal 3-Hole Shell	64
85-9843	Metal on Metal 3-Hole Shell	66
85-9844	Metal on Metal 3-Hole Shell	68
85-9845	Metal on Metal Standard Insert	28, 0°
85-9846	Metal on Metal Augmented Insert	28, 10°

Control Products (commercially available)

Reference No.	Description	Size
85-1410	P.F.C. Apical Hole Plug	One Size
55-7048	ZTT II 3 Hole Shell (DP)	48
55-7050	ZTT II 3 Hole Shell (DP)	50
55-7052	ZTT II 3 Hole Shell (DP)	52
55-7154	ZTT II 3 Hole Shell (DP)	54
55-7156	ZTT II 3 Hole Shell (DP)	56
55-7158	ZTT II 3 Hole Shell (DP)	58
55-7160	ZTT II 3 Hole Shell (DP)	60
55-7162	ZTT II 3 Hole Shell (DP)	62
55-7164	ZTT II 3 Hole Shell (DP)	64
55-7166	ZTT II 3 Hole Shell (DP)	66
55-7354	ZTT II 3 Hole Shell (DP+6)	66
55-7356	ZTT II 3 Hole Shell (DP+6)	56
55-7358	ZTT II 3 Hole Shell (DP+6)	58
55-7360	ZTT II 3 Hole Shell (DP+6)	60
55-7362	ZTT II 3 Hole Shell (DP+6)	62
55-7364	ZTT II 3 Hole Shell (DP+6)	64
55-7366	ZTT II 3 Hole Shell (DP+6)	66

Reference No.	Description	Size
55-0235	Locking Pins	3.5 mm dia
55-0295	Locking Pins	5 mm dia
52-0826	Poly-Dial Insert, 0°	26
55-1916	Poly-Dial Insert, 10°	26
52-0528	Poly-Dial Insert, 0°	28
52-0628	Poly-Dial Insert, 10°	28
55-7099	ZTT Apical Hole Plug	

4.2 Femoral Components

Femoral components used for control and experimental groups will be standard commercially available S-ROM Hip system femoral components and sleeves.

4.3 Femoral Heads

Femoral heads used with the control product will be standard commercially available S-ROM Femoral heads.

Due to the tighter tolerancing requirements for the experimental device articulation, the S-ROM Femoral Heads for use with the experimental acetabular components have been designated with separate reference codes.

Reference No.	Description	Size
85-9913	MOM Femoral Head (S-ROM)	28 + 0
85-9915	MOM Femoral Head (S-ROM)	28 + 6
85-9916	MOM Femoral Head (S-ROM)	28 + 12

5. Ethics and Legal Approval

This study will be conducted in the United States under a FDA approved Investigational Device Exemption (IDE). The study sponsor, Johnson & Johnson Professional, Inc., will oversee all aspects of the study including compliance with all applicable laws and regulations. Participating investigators will understand and accept their responsibilities prior to study initiation.

6. Patient Selection

6.1 Inclusion Criteria

Indications for use of the MOM Hip System are current indications for hip arthroplasty including a Harris Hip Score of <70 with at least moderate pain. Subjects may not be included unless they meet the inclusion criteria. Subjects must be candidates for a total hip system. Disease states associated with hip arthroplasty are:

Osteoarthritis

Post-traumatic arthritis

Avascular necrosis

Limit to Steinberg Grade IV or above

Developmental hip dysplasia

Protrusio acetabula

Slipped capital femoral epiphysis

Crystalline arthropathy

6.2 Criteria for Exclusion

In order to be considered for inclusion into the study, patients must not meet any of the following exclusion criteria. These criteria should be reviewed prior to seeking informed consent from the potential subject.

Previous hip arthroplasty/revision on affected hip

Harris Hip Score ≥ 70 with mild or no pain

Metabolic disorders of calcified tissues; e.g. Paget's disease

History of recent joint sepsis

No active infection of the joint during the previous six months

Charcot neuropathy

Psycho-social disorders that would limit rehabilitation

Patients must have sufficient mental awareness to understand and agree to the required rehabilitation steps

Skeletal immaturity

Rheumatoid or other inflammatory arthritis

Greater than 75 years of age at the time of surgery

Severe osteoporosis

Exclude patients with indication of severe osteoporosis noted on standard x-ray. Singh Index I

Ipsilateral knee/ankle pain deformity

Severe involvement of other joints of affected limb which would impact rehabilitation

Patients requiring or expecting to require cytotoxic agents or therapeutic radiation

Exclude patients requiring or expected to require over course of protocol

Patients requiring non topical immunosuppressive agents, including corticosteroids

Exclude if requirement exceeds thirty days within three months prior to enrollment or is anticipated during the first six months after surgery. This must be determined at the time of pre-operative examination.

Known requirement for adjunct fixation

Expected need for greater than 10° acetabular liner augmentation

6.3 Available Alternate Treatments

Conservative, non-surgical treatment

A conventional hip joint that uses cement on the ball (and stem) and on the socket

Bipolar Hip replacement

Hip fusion

7. Study Design

A maximum of three hundred subjects who meet the inclusion criteria will be entered into this study arm. Please refer to section 16, Statistical Analysis for a discussion of the sample size. They must not meet any of the exclusion criteria, and must understand the experimental nature of the procedure and document their consent to participate by signing the Informed Consent documents.

Subjects entered into the study may be of either sex.

Randomization will be utilized to limit the differences between the two study groups. The surgical technique for implanting the components varies little. The femoral components are commercially available product and are the same for both study groups. The acetabular shell components are very similar in profile and fixation surface. They differ in liner capture mechanism. The acetabular liners represent the major difference between the two systems, that difference being the use of either a metal (EXP) or a polyethylene (CTL) bearing surface.

Each participating subject will be assigned an ID number that will be used throughout the study. If a patient is a candidate for bilateral hip arthroplasty, both hips will receive the same randomization designation based on the initial randomization card drawn.

~~XXXXXXXXXX~~

Each participating subject will be assigned an ID number that will be used throughout the study. If a patient is enrolled for bilateral hip surgery, two different ID numbers will be assigned one for each enrolled side. Study group assigned (EXP or CTL) will be determined by drawing consecutively numbered, sealed envelopes after the patient has been evaluated for entry and exclusion criteria and has completed the informed consent process.

Each patient entered into the study will have demographic data and pertinent past history recorded on the Patient Entry Form (Form 11). All Case Report Forms (CRF) are included in APPENDIX B.

If, at surgery, the investigator determines that a patient is not a suitable candidate for the components allowed by this protocol the patient will not be enrolled in the study. Conventional components will be implanted. Records will be maintained for any patients who are dropped from the study for this reason.

Adjunct acetabular fixation may be used if necessary during surgery. Dome screws used in conjunction with the experimental acetabular components are limited to sizes 6.5mm x 25 and 6.45mm x 45 (Reference Numbers 55-6072→ 55-6076).

The immediate post-operative care is no different from other total hip prosthesis procedures. All subjects will be restricted to 50% weight bearing with bilateral support (two crutches/walker) for six weeks post-op. In addition, daily exercises including isometric and stretching exercises for at least 15 minutes, three times per day as capable are recommended. Subjects will be scheduled for post-operative evaluation at discharge from hospital, at 6 weeks and at 6, 12, and 24 months. Any subject failing to appear for examination dates will be contacted in order to secure return. Some variation of examination dates or some missed examinations will not adversely affect the validity of the study.

Patients who have completed the 24-month evaluation period will be followed at least once every two years with the routine follow-up evaluation for the duration of the study.

Observations regarding pain, function, range of motion and deformity will be assigned a point value and will be used to produce a hip rating score. Routine radiographs taken during each follow-up exam will be examined for lucencies or evidence of component loosening. At each scheduled visit, a review of complications/adverse events (device-related or not) will be conducted and will be recorded on case report forms and reported.

If it is determined that revision surgery is required, a Re-Operation Form (Form 61) will be completed identifying the reason for the procedure. Any individual who undergoes revision procedure will be followed for the duration of the study.



8. Observations

Note: All CRF's will include a patient ID field and an optional patient initials field. The affected side is also included on each CRF. Each form contains a region to enter comments and a signature line.

Patient Entry (Form 11)

<p>Bilateral Study Patient</p> <ol style="list-style-type: none"> 1. No 2. Yes 	<p>Has subject previously been enrolled into this clinical trial for the other hip? Please enter the ID assigned to the patient for the other hip</p>
<p>Demographics</p> <ol style="list-style-type: none"> 1. Birth Date 2. Gender 3. Height and height unit 4. Weight and weight unit 	
<p>Duration of Symptoms, in years</p>	<p>Time in years that symptoms have occurred more than 2 weeks per month rounded by > 6 go to next year. Best estimate</p>
<p>Patient Aware of any Allergies</p> <ol style="list-style-type: none"> 1. None 2. To metals 3. To drugs 	
<p>Review of Exclusion Criteria*</p> <p>Patient must not meet any of these criteria as a condition of enrollment</p> <ol style="list-style-type: none"> 1. None 2. Previous hip arthroplasty/revision 3. HHS \geq 70 with mild/no pain 4. Calcified tissue disorders 5. History of recent joint sepsis 6. Charcot neuropathy 7. Psycho-social disorders that would limit rehabilitation 8. Skeletal immaturity 9. Rheumatoid or other inflammatory arthritis 10. Greater than 75 years of age 11. Severe Osteoporosis 12. Severe pain or deformity of knee or ankle on the affected side 13. Currently uses or requires cytotoxic agents or therapeutic radiation 14. Use of Immunosuppressants (includes corticosteroids) 15. Known requirement for adjunct acetabular fixation 16. Expected need for greater than 10° acetabular liner augmentation 	<p>Any type of previous hip arthroplasty on this side. Harris Hip Score</p> <p>No active infection of the joint during the previous 6 mos.</p> <p>Radiographic observation of thinning Singh Index Grade I</p> <p>At the time of enrollment or use is anticipated within the study period</p> <p>Use exceeds 30 days and occurs within 3mo. of enrollment or is anticipated within 6 mo. of surgery This must be determined at the time of pre-operative examination</p> <p>This must be determined at the time of pre-operative examination</p>

Patient Entry (Form 11) (cont.)

<p>Primary Presurgical Diagnosis</p> <ol style="list-style-type: none"> 1. Osteoarthritis 2. Post Traumatic Arthritis 3. Avascular Necrosis 4. Developmental Hip Dysplasia 5. Protrusio acetabula 6. Slipped capital femoral epiphysis 7. Crystalline Arthropathy 	<p>Steinberg Scale \geqIV</p>
<p>Compromising Factors</p> <ol style="list-style-type: none"> 1. Unilateral hip disease 2. Bilateral hip disease or moderately limiting condition 3. Multiple joint involvement or severe limiting condition 	<p>Unilateral hip disease; no other limiting conditions. Include patient in group 1 if patient has a well-functioning THR on the contralateral side</p>
<p>Coexistent disease</p> <ol style="list-style-type: none"> 1. None 2. Hypertension 3. Thromboembolism 4. Varicose Veins 5. Cardiovascular 6. GI 7. Respiratory 8. Renal 9. Hepatic 10. Diabetes 11. Endocrine 12. Musculoskeletal 13. Neurological 14. Other 	<p>Subject currently under treatment for</p> <p>Please describe</p>
<p>Current Status of other joints</p> <ol style="list-style-type: none"> 1. Ipsilateral knee 2. Ipsilateral ankle 3. Ipsilateral upper extremity 4. Contralateral hip 5. Contralateral knee 6. Contralateral ankle 7. Contralateral upper extremity 	<p>Rate as: none, moderate, severe, replace or fused No severe rating No severe rating</p>

PRE-OPERATIVE OBSERVATIONS

Observations noted below will be made for each patient enrolled into the study. Observations recorded in the four categories: pain, function, range of motion and absence of deformity will be assigned a point score modified from Harris, (Journal of Bone and Joint Surgery, Vol. 51-A, p. 737).

The point values, where applicable, are included in the observation description. Categories have been modified to comply with joint recommendation of the Hip Society, SICOT and the American Academy of Orthopedic Surgeons as described in the Journal of Bone and Joint Surgery, Volume 72-A, No. 2.

Pre-Operative Observations (Form 12)

Date of Evaluation	
Pain Information Pain 1. None 2. Slight 3. Mild 4. Moderate 5. Marked 6. Totally Disabled	Patient comment regarding level of pain in operated hip (44 pts) No pain or ignored (38) Occurs occasionally; no compromise in daily activities (30) No limitation of ordinary activity, rarely moderate pain with unusual activity. May take aspirin (20) Tolerate but requires concession. Some limitation of ordinary activity or work. May require occasional pain medicine stronger than aspirin (10) Serious limitations of activities (0) Crippled by pain, bedridden
When Does Pain Occur 1. Never 2. With first steps, then dissipates 3. Only after long (30 min) walks 4. Both with first steps and after long walks 5. With all walking 6. At all times	This response is a combination of 2 and 3 But not during rest

Pre-Operative Observations (cont.) (Form 12)

<p>Pain Location If multiple location, describe location where pain most severe</p> <ol style="list-style-type: none"> 1. None 2. Groin 3. Buttock 4. Hip Joint 5. Thigh 	<p>Most severe</p>
<p>Function</p>	<p>As noted on operated side</p>
<p>Gait Limp</p> <ol style="list-style-type: none"> 1. None 2. Slight 3. Moderate 4. Severe 	<p>(11 pts) 100% weight bearing on affected side (8) 66-99% weight bearing on affected side (5) 33-65% weight bearing on affected side (0) 0-33% weight bearing on affected side</p>
<p>Support - required to walk comfortably and smoothly</p> <ol style="list-style-type: none"> 1. None 2. Cane, long walks 3. Cane, mostly 4. One crutch 5. Two canes 6. Two crutches 7. Walker 8. Not walking 	<p>(11 pts) (7) (5) (3) (2) (0) (0) must specify reason (Harris, 1968) ability to walk on a regular basis</p>
<p>Distance Walked</p> <ol style="list-style-type: none"> 1. Unlimited 2. Six blocks 3. Two or three blocks 4. Indoors only 5. Bed and chair 6. Unable 	<p>(11 pts) (8) (5) (2) (0) (0)</p>

Pre-Operative Observations (cont.) (Form 12)

Activities	
Stairs Ascending and Descending 1. Normally 2. Able, rail 3. Any Manner 4. Unable	(4 pts) foot over foot, does not require railing (2) foot or foot, must use railing (1) stairs in any manner (0)
Enters car or public transportation 1. Yes 2. No	Evaluate ability to get into car or public transportation (1 pt) (0)
Sitting 1. Comfortable 2. Limited 3. Unable	(5 pts) in normal chair for one hour (3) one half hour on a high chair (0)
Sitting to Standing 1. No Assistance 2. With upper extremity 3. Unable	Able to raise from chair without use of upper extremity Able to rise from chair using arms Requires assistance of another
Shoes and Socks 1. With ease 2. With difficulty 3. Unable	(4 pts) puts on socks and ties shoes with ease (2) puts on socks and ties shoes with difficulty without assistance (0)

Pre-Operative Observations (cont.) (Form 12)

Range of Motion	Range	X Index =	Maximum Value
1. Flexion	0-45°	1.0	45
	45-90°	0.6	27
	90-110°	0.3	6
	110-130°	0.0	0
2. Abduction (in extension)	0-15°	0.8	12
	15-20°	0.3	1.5
	20-45°	0.0	0
3. External Rotation (in extension)	0-15°	0.4	6
	>15°	0	0
4. Internal Rotation (in extension)	Any	0	0
5. Adduction (in extension)	0-15°	0.2	3
	Over 15°	0	0
Total possible motion point value X overall factor 0.5 =			100.5
Absence of Deformity		Requires all four (for a total of 4 pts.)	
1. Fixed flexion contracture		less than 30°	
2. Fixed adduction		less than 10°	
3. Fixed Internal rotation		less than 10° measured in extension	
Limb length discrepancy		less than 3.2 cm	
1. None			
2. Shorter			
3. Longer			
Summary Scoring System			
1. Pain		(44 pts)	
2. Function		(47)	
3. Deformity		(4)	
4. Range of Motion		(5)	
Total			
Trendelenburg Sign		Affected side	
1. Negative			
2. Positive			
3. Unable to test			

Pre-Operative Observations (cont.) (Form 12)

<p>Medication Indicate if any of the listed medications are taken routinely</p> <ol style="list-style-type: none">1. None2. ASA3. NSAIDS4. Oral steroids5. Narcotic analgesics	<p>≥ 4 times per week Please indicate if medication is taken for: Affected hip Other problem Both</p>
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Pre-Operative Radiographs (Form 15)

Radiographic Observations - AP and Lateral View

Date of radiograph	
Femoral deformity Each is rated a No or Yes 1. Head 2. Neck 3. Shaft	
Femoral intramedullary flare 1. champagne glass 2. proportional 3. stovepipe	A B C
Joint space	mm
Osteoporosis 1. Type I 2. Type II Grade of osteoporosis	Postmenopausal (within 15-20 yrs. of menopause) affects mostly trabecular bone Senile osteoporosis (men and women over age 70) affects cortical and trabecular bone equally Using the Singh Grade 2,3,4,5,6; Singh Grade 1 see exclusion criteria
Osteophytes 1. In joint space 2. At joint margin	Mark all that apply
Acetabular Description 1. Normal 2. Enlarged 3. Medial wall defect 4. Anterior rim defect 5. Posterior rim defect 6. Dome defect	Mark all that apply
Acetabular Dysplasia 1. No 2. Yes, mild 3. Moderate 4. Severe 5. Pseudo-acetabulum	
Acetabular Protrusio 1. No 2. Yes	mm
Ectopic Ossification 1. None 2. Brooker I 3. Brooker II 4. Brooker III 5. Brooker IV	

Operative Observations (Form 21)

Date of Procedure	
Operation time, skin to skin	
Surgical Approach 1. Posterior lateral 2. Posterior medial 3. Watson-Jones/anterior lateral 4. Anterior medial 5. Direct lateral 6. Other	Please describe
Components Implanted For each unit, provide the reference number and the lot number 1. Femoral Stem 2. Femoral Head 3. Femoral Sleeve 4. Acetabular shell 5. Acetabular liner	
Locking of Polyliner 1. 3.5 Locking Pins (55-0235) 2. 5.0mm Locking Pin (55-0295) 3. Peripheral Screws Placed	Control device only Enter reference number
Dome Screws Placed 0 None 1 One 2 Two 3 Three	
Trochanter 1. On 2. Off 3. Slide	

Operative Observations (cont.) (Form 21)

Acetabulum Reamed	
1. No 2. Yes	Last reamer used (mm)
Depth of subchondral plate 1. Intact 2. Reamed through	
Acetabular/Femur bone graft placed 1. No 2. Yes, morcellated bone 3. Yes, bulk autograft 4. Yes, bulk allograft	
Subchondral Bone Drilled/Acetabular/Femur 1. No 2. Yes	
Acetabular Cyst(s) 1. None 2. Present, no intervention 3. Present, curetted 4. Present, curetted and grafted	
Bone Strength Acetabular/Femoral 1. Normal/Sclerotic 2. Cystic 3. Porotic	

Discharge Observations (Form 31)

Date of Discharge	
Patient discharged to rehab facility 1. No 2. Yes Date of Discharge from Rehab Facility	
Medications prescribed at discharge 1. None 2. NSAID 3. Oral Steroids 4. Narcotic 5. ASA 6. Coumadin 7. Heparin 8. LMWH 9. Other	Please indicate if medication is taken for: affected hip other problem both Low Molecular Weight Heparin
Post-operative wound complications 1. No 2. Yes	Mark all that apply
Complications 1. Hematoma 2. Superficial infection 3. Drainage, C&S negative 4. Drainage, C&S positive 5. Deep infection 6. Other	Please define resolution dates Report severity as mild, moderate or severe Please describe

Follow-Up Observations (Form 41)

This form is completed at each follow-up interval and if the patient appears for an extra visit due to a problem with the affected hip joint. It contains the same information as the Pre-Operative Observation Form (Form 12) with the addition of an indication of follow up examination visit and a check for complications.

Protocol visit identification	Evaluation
Complications	
NOTE: All complications should be reported on Form 51 1. None 2. Yes	All information reported on Complication Form 51 Yes, please describe

Follow-Up Radiographs Femoral Component (Form 46)

Form is completed at all Post-operative visits beginning with the 6-week visit.

Protocol visit identification	Evaluation
Date of radiography	
Stem type	Cemented/cementless
Migration of Stem 1. None 2. Migration into valgus 3. Migration into varus	
Subsidence Related to fixed landmarks on femur; proximal tip of greater trochanter and mid-point of lesser trochanter 1. No 2. Yes	Provide distance in mm
Ectopic Ossification 1. None 2. Brooker I 3. Brooker II 4. Brooker III 5. Brooker IV	Islands of bone within soft tissue Bone spur at end of pelvis or femoral head leaving 1 cm Islands of bone within soft tissue bone spur at end of pelvis or femoral head leaving <1 cm Ankylosis
Resorption of Medial Femoral Neck (calcar) 1. No 2. Yes	Loss of height and loss of thickness in mm
Radiolucency 1. None 2. Yes	Enter AP or Lateral Enter lucency: prosthesis-bone prosthesis-cement cement-bone resorption hypertrophy Enter thickness in mm for zones 1 through 7
Loss in bone density 1. No 2. Yes	Enter AP If yes, Patchy loss Uniform loss Increased Trabecular bone Endosteal cavitation lysis Enter thickness in mm for zones 1 through 7

Follow-Up Radiographs of Acetabular Component (Form 45)

Form is completed at all post-operative visits beginning with the 6-week visit.

Protocol visit identification	Evaluation
Date of radiography	
Inclination of cup (abduction) in degrees Version of Cup 1. Neutral 2. Retroverted 3. Anteverted 4. Not measurable	Provide degrees
Acetabular Radiolucency 1. No 2. Yes	Enter AP Enter lucency in mm for Zones 1 through 3
Location of center of rotation of hip relative to teardrop, in mm 1. Superior 2. Medial	
Appearance of acetabular bone graft 1. None 2. No change 3. Densified 4. Absorbed	No graft present since initial postoperative exam
Acetabular Radiographic Complications Report any Radiographic Complications Noted at this Follow-up Visit 1. No 2. Yes	If yes, provide details on Complications Form 51

Complication Observations (Form 51)

In the event of any severe/unanticipated complications, sponsor must be immediately notified. Observations will be recorded.

Report date	
Date of complication onset	
Date of complication resolution	
Was the complication confirmed by radiograph 1. Yes 2. No	
Date of radiograph	
Complication 1. Dislocation 2. Fracture of acetabulum 3. Fracture of femur 4. Implant loosening 5. Implant failure 6. Indication of debris 7. Superficial wound infection 8. Deep joint infection 9. Other	Mark one only. Use a separate Form 51 for each complication Please describe
Severity of complication 1. Mild 2. Moderate 3. Severe	
Affected components	All that apply
Intervention 1. None 2. Medical 3. Other conservative therapy 4. Surgical	Enter date of intervention and specify type If surgical intervention is required, please complete Reoperation Form 61

Withdrawal/Termination Report (Form 71)

This form is used to report any patient who leaves the study by request or because of loss to follow-up.

Effective Date	
Reason for Withdrawal 1. Patient request 2. Patient refused to return 3. Lost contact 4. Death 5. Other	Date Please explain

9. Adverse Reactions

All adverse reactions occurring during the study, including the nature, severity and relation to the test article of any such reaction, will be reported on the appropriate case report form. Additionally, unusually severe adverse reactions shall be reported immediately by telephone to the sponsor. The sponsor will work with the investigator to determine if the reaction is an unanticipated adverse reaction.

A report of any unanticipated adverse reactions shall be submitted to the sponsor and the reviewing Institutional Review Board as soon as possible, but no later than ten (10) working days after the investigator first learns of the effect. Reports should be submitted to the Clinical Research Associate.

Wini T. Dillon
Manager of Clinical Research
Johnson & Johnson Orthopedics, Inc.
325 Paramount Drive
Raynham, MA 02767
Office: (508) 828-3415
Home: (781) 575-9467

Cyrus Guidry
Director, Clinical Research
Johnson & Johnson Orthopedics, Inc.
Raynham, MA 02767
Office: (508) 880-8124
Home: (617) 763-6311

10. Evaluation of Data

All experimental observations will be entered on the appropriate case report form for each subject. A separate CRF is provided for use if any subject undergoes a second operative procedure on the replaced hip (Case Report Form #61).

All data are forwarded to the sponsor for data entry and analysis. Any complications reported are assessed as received. On a periodic basis, data will be reviewed for any indication of trends.

11. Study Duration

It is anticipated that the study will be completed within four years, assuming adequate patient entry. The sponsor reserves the right to discontinue the study with suitable notice to the investigator in writing.

12. Loss or Removal of Subject

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 exam will be contacted by mail or telephone in order to secure attendance. If the subject moves from the area, contact through an orthopedic surgeon local to the subject's new community will be attempted. Difficulty in securing follow-up is not anticipated as repeated follow-up examinations are considered an essential component of any total joint arthroplasty procedure.

13. Clinical Supplies and Monitoring

The investigator will maintain an inventory of all experimental supplies under his supervision as well as a record of the quantity and lot number(s) of all test articles.

At the conclusion of the study the investigator shall return to the sponsor any remaining supply of the test material or otherwise dispose of the device as the sponsor directs.

The investigator will permit a representative of the sponsor's monitoring team to review all case report forms and study related adjunctive data at regular intervals throughout the study. These reviews are for the purposes of verifying the adherence to the protocol and the completeness and exactness of the data being entered as required by Federal Regulations.

14. Patient Consent

Written informed consent will be obtained from all patients or responsible representatives, who will be properly informed as to the reason for this study, potential risks and benefits of the treatment applied and alternatives to the test treatment.

15. Alterations of Protocol

No changes of the protocol with the exception of those of emergency nature will be made without written consent from the sponsor and by mutual agreement between the investigator and sponsor. All changes will be recorded by the investigator and submitted to the sponsor, and the investigator's governing IRB.

The sponsor will obtain written approval for changes in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects from FDA, prior to initiating such changes.

16. Statistical Analysis

The study is designed as a randomized controlled clinical trial. Both arms will follow the same protocol. Each arm will include a maximum of 300 patients (150 in each study group). This sample size will be able to determine whether the treatment group is equivalent to the control group. Equivalence is defined as a difference between two-year survival of less than .08 (control group minus treatment group).

Estimated sample size requirements were determined based upon the following assumptions:

Current (control) success rate of	0.98
Projected experimental rate of	0.98
Equivalency (Control - Experimental)	<.08
Test type	X ² Test of Equivalence
Type I Error	$\alpha = .05$
Type II Error	$\beta = .05$

Not more than 20% of patients failing to complete the 2 year protocol

Based upon these assumptions, a sample size of 125 will yield a test with 95% power to determine whether the two groups are equivalent.

A baseline analysis of the experimental and control populations will be performed to determine whether the random assignment resulted in equivalent experimental and control groups. Tabulations of Age Group, Primary Diagnosis, Coexistent Disease and Status of Other Joints reported on pre-operative data collection forms will be compiled for comparison.

An analysis of safety and effectiveness data comparing experimental and control groups will be performed. The following variables will be included:

- a) Implant Survival
- b) Hip Score
- c) Pain Rating

Hip implants that undergo a revision surgery that involves the recommended replacement of any hip component will be classified as a failure. In addition, any

patient with a pain rating of moderate or worse in the affected hip, at 24 months will be considered a failure. Success is defined as any 24-month post-operative Harris Hip Score that is ≥ 70 and is accompanied by mild to no pain. Survival curves will be calculated for the experimental and control groups. These curves will be compared using the Log-Rank Test. Hip Scores and Pain Ratings will be analyzed simultaneously with a multiple analysis of variance (MANOVA) to identify any differences between experimental and control groups. This overall test will assure that the α of 0.05 will apply to both dependent variables simultaneously (family α 0.05). If a statistically significant difference is observed then a Student's t- Test for independent means will be performed on each dependent variable.

These analyses will be performed on all data collected at the two-year post-operative examination. A similar analysis will be performed on the last available follow-up data. Subjects with only six-month data will be excluded from this analysis because these data are considered to be within the initial healing and adjustment period and are not representative of the long term result.

Baseline analyses will be performed to compare pre-operative characteristics (e.g. Age, Primary Diagnosis, Coexistent Disease and Status of Other Joints) of those lost to follow-up with those in the final cohort in order to assess bias due subjects lost to follow-up. Study center effects will be explored by comparing the major outcomes across study centers.

A Logistic Regression analysis will be performed to determine whether there are any associations between pre-operative characteristics and post-operative survival. Hip Score and Pain Rating will be evaluated in a similar manner using stepwise multiple regression.

When actuarial analysis indicates that there are 100 unilateral patients in each group with 24-month data available, analysis will be completed on these patients and enrollment will be terminated.

17. Analysis of Protocol

Data collected in four categories; pain, function, absence of deformity and range of motion, will be applied to the rating scale proposed by Harris (J. of Bone and Joint Surgery, Vol 51-A: 737, June 3, 1969). The use of a rating system provides a reproducible and reasonable objective system for combining important variables into a single figure.