

Investigational Plan Metal on Metal Acetabular System

Purpose and Objectives

This study is to be conducted to investigate the safety and effectiveness of a metal on metal bearing surface. The main objective of this investigation is to determine the safety and effectiveness of the Metal on Metal Articulating Acetabular system.

The study will include a randomized, concurrent control group existing of conventional total hip prosthesis. Each surgery will include the use of either a Metal acetabular liner (experimental group) or a UHMWPE Polyethylene acetabular liner (control group). The device will be used in conjunction with one of Biomet's various metal acetabular shells, femoral hip components and cobalt-chromium modular femoral heads. The Metal on Metal study is limited to non-cemented component application only.

The acceptability of the effectiveness of the metal on metal device is to be determined primarily by comparison of function and pain, both preoperatively and postoperatively and between the metal on metal devices and conventional UHMWPE devices. Secondly, the effectiveness will be determined by radiographic evaluation. The safety of the metal on metal acetabular device will be determined by the incidence of complication, device related or otherwise, and revision between the device and the conventional acetabular systems.

The study will be conducted over a period of five years and will contain a maximum of 196 cases - 98 cases in the experimental group and 98 cases in the control group. Approximately eight to ten investigators will participate in this study.

Protocol

I. Indications

The indications for enrollment into this study consist of only the following diagnostic group:

Noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, subcapital fracture, legg perthes, slipped capital epiphysis, fused hip, fracture of the pelvis, or diastrophic variant.

Selection of candidates for this study include the following considerations:

- 1) A preoperative level of function and pain the same as for conventional hip replacement procedures.

- 2) A likelihood of obtaining relief of pain and improved function.
- 3) Full skeletal maturity.
- 4) Ability to follow instructions.
- 5) Good general health.
- 6) Willing to return for follow-up evaluations.
- 7) No bias to sex.

II. Patient Exclusion

Patients displaying the following contraindications shall be excluded from this investigation:

- 1) Any patients diagnosed as Rheumatoid, Deformity, Revision, as well as, bi-lateral cases.
- 2) Infection.
- 3) Osteoporosis, or marked bone loss which would preclude proper fixation of the prosthesis.
- 4) Uncooperative patient, predictably unable to get long-term follow up.
- 5) Parkinson's disease.
- 6) Vascular insufficiency, muscular atrophy, or neuromuscular disease in the affected limb.
- 7) Severe instability or deformity of the ligaments and/or surrounding soft tissue which would preclude stability of the device.
- 8) Pregnancy.

III. Evaluation and Follow-up

Patient packets containing all of the necessary forms for the duration of the investigation will be supplied to each investigator prior to the initiation of the study. Samples of these forms have been included.

Preoperatively, a signed "Informed Patient Consent" will be obtained from each patient. A "Patient Historical Record" will be completed. Diagnosis may include any confirmatory test as deemed appropriate by the surgeon such as x-ray, sedimentation rate, latex fixation test or rheumatoid factor. Standard preoperative blood and lab work should be conducted.

An "Operative Record" will be completed immediately following surgery to detail the procedure and any complications.

Data to determine clinical efficacy will be collected on the "Preoperative Analysis and Follow-up Record". This hip evaluation form based on the Harris Hip Scale, will be completed preoperatively and postoperatively, at six months, twelve months, and yearly for at least five years thereafter. A score of 90-100 is an excellent result, 81-90 is good, 71-80 is fair, and 70 or below is poor. Patients with classification of fair or below at 1 year post-implantation or later, with no external complications (i.e. trauma, failing health) will be considered failures.

In addition, efficacy data concerning bone apposition will be determined using radiographic evidence with postop x-rays as the control. Initially, all x-rays for each case will be reviewed by the respective investigator and/or radiologist. The radiographs will be reviewed for rotation and/or settling of the component, and any presence of radiolucent lines surrounding the device. The patients will have an x-ray immediately postoperatively, and at each regularly scheduled hip evaluation as outlined above.

Safety of the device will be determined by comparative analysis of complication rates. All complications and adverse reactions, device related or otherwise will be reported and recorded on the "Special Report Form". The data and reason for a patient becoming lost to follow-up will also be recorded on the form. Any and all adverse effects whether device related or not will be recorded and reported in all progress reports. In the event that the this Metal on Metal study should be closed or terminated, at least a 24 month follow-up evaluation will be conducted for all patients entered into the investigation.

IV. Risk Analysis

All of the risks common to conventional joint replacement are possible with this device as are certain risks associated with any invasive procedures. A full risk analysis assessment has been done and has been amended to this document.

Potential risks common to conventional joint replacement include:

- 1) Infection.
- 2) Damage to surrounding tissues, cartilage or tendons.
- 3) Long term swelling.
- 4) Excessive bleeding.
- 5) Delayed wound healing.
- 6) Major nerve or blood vessel injury.
- 7) Fracture.
- 8) Instability.
- 9) Loss of motion.
- 10) Risks associated with the anesthetic such as permanent brain damage, pneumonia, blood clots, heart attack and death.

Some complications may cause a draining wound, the need for further surgery, prolonged or permanent pain, deformity and inconvenience for the patient.

Potential risks associated with the use of the metal on metal acetabular system include:

- 1) Dislocation of the prosthesis.
- 2) Disassociation of the liner from the acetabular shell.
- 3) Metal debris.

This investigational plan has reduced the potential risk to the patient through the following methods:

- 1) by defining a patient population that limits the exposure of the device to patients conforming to the proposed indications, exclusions, and age requirements.
- 2) the surgical technique has been developed to eliminate potential operative difficulties.
- 3) a conservative postoperative rehabilitation regime has been developed to allow the patient mobility without compromising fixation of the device.

V. Patient Population

- 1) Sex - Patients will be selected without bias as to sex.
- 2) Age - Patients will be limited to those patients who have reached full skeletal maturity.
- 3) Population - An initial population of 196 cases in both the experimental and control groups will be enrolled.

VI. Anticipated Changes

It is anticipated that during the course of the study, certain changes may become desirable. These changes may include additional sizes of all components based on patient requirements. In addition, development of unique instrumentation for the implantation of this device is on going.

Any deviation from the stated protocol will be made only in an emergency situation unless the investigator has obtained prior approval from the FDA and the appropriate institutional review board (IRB).

**Metal on Metal Acetabular System
Randomisation Procedure**

The FDA has designated this clinical study to be a randomized concurrent study, i.e. the investigator will not be advised as to what device a patient will receive at his/her time of consultation.

Here are some guidelines to help you in the process:

1. At the time of consultation, when the patient has agreed to be entered into the study knowing that they may or may not receive the experimental device, please have them sign the consent form. Also complete the Historical and Pre-op Harris Hip Evaluation forms.
2. Upon a patient enrollment the investigator can either call Kara Schwartz at Biomet at (219) 267-6639 ext. 1761 or call the local Biomet representative (who will then call Biomet) with the patient's name, date of surgery, and his/her diagnosis.
3. According to the randomization scheme the patient is assigned either a Metal on Metal (experimental) device or a polyethylene (control) device.
4. If the patient is to receive the experimental device, the Metal on Metal device will be shipped out only upon release by Biomet's Regulatory Department. Release of the Metal on Metal devices will be on a per case basis.

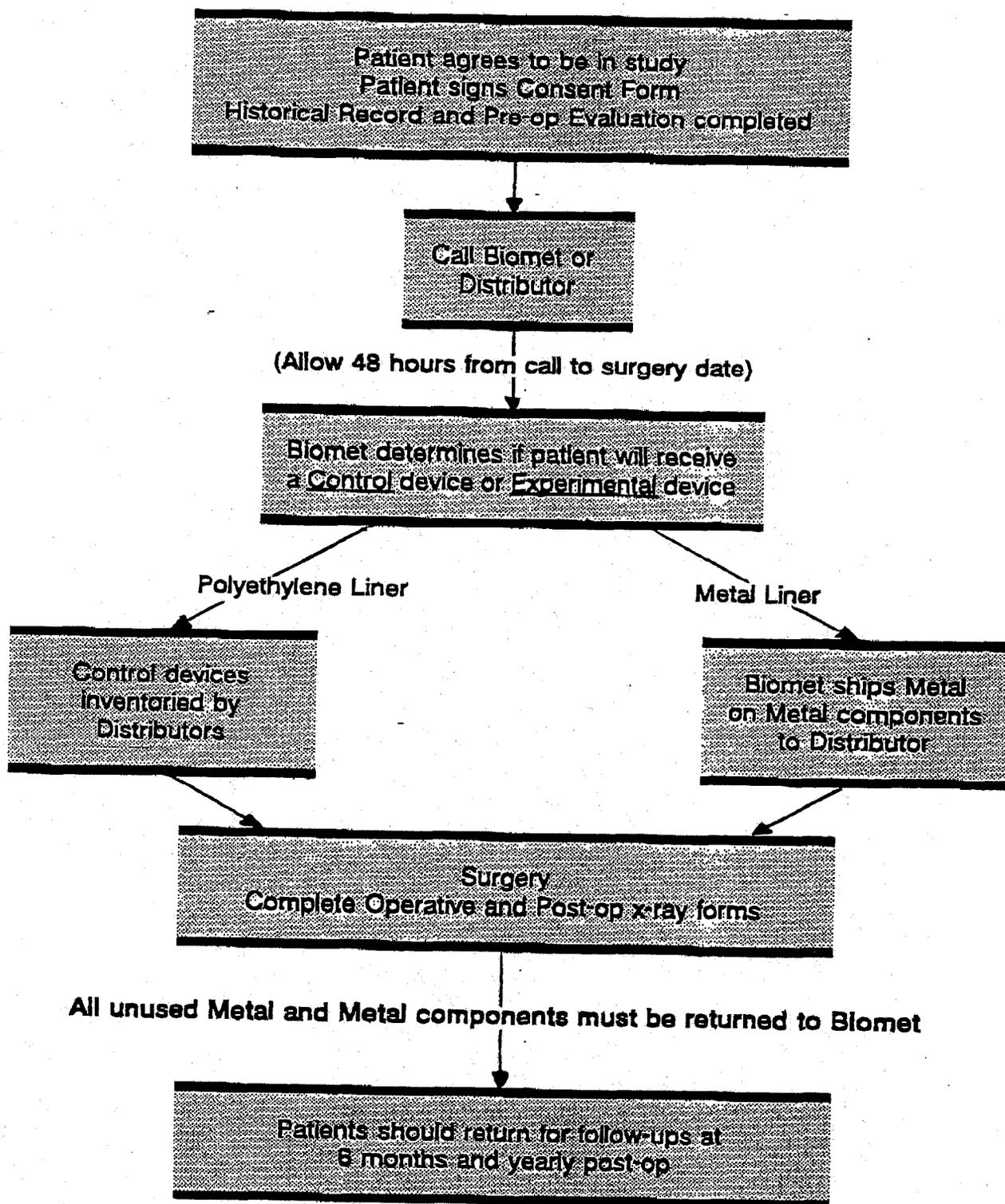
At least 48 hours is required from time of phone call to date of surgery to allow for shipping time of the Metal on Metal devices. Standard polyethylene (control) devices are inventoried and available at the local distributor.

All Metal on Metal components not implanted must be returned to Biomet.

5. Surgery date: all components are to be non-cemented. Complete Operative and Post-operative x-ray analysis forms for control and experimental patients.
6. Patients should return for their follow-up exams at 6 months, and yearly following surgery. The white copy of the forms are to be returned to Biomet.

The patient's full cooperation in returning for their follow-ups as well as completed clinical data forms are important. Please be aware that the data we obtain and compile will be instrumental in allowing future general marketing of the device.

Metal on Metal Acetabular System Study Procedures



Complete all forms and return white copies to Biomet.