

# Functional Outcomes in Patients with Displaced Femoral Neck Fractures Undergoing Hemiarthroplasty vs. Total Hip Arthroplasty: A Prospective Randomized Controlled Trial

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## A. Study Purpose and Rationale

### a. Introduction

According to the American Academy of Orthopaedic Surgeons, there are 350,000 annual hospital admissions in the United States resulting from hip fractures and the number is expected double to 700,000 by the year 2050<sup>1</sup>. This dramatic increase in hip fractures may reach epidemic proportions in the coming decades because of the anticipated explosion in the size of the over-65 years of age population, the concomitant gradual increase in average life span, and the expected growth in the numbers of individuals suffering from osteoporosis. Currently, the one year mortality rate in the elderly for hip fractures can be as high as 36%<sup>2, 3</sup>, and of those who survive hip fractures, it is estimated that only one-third of these patients will return to a lifestyle that approaches their pre-fracture status<sup>4-6</sup>.

Although both hemiarthroplasty and total hip arthroplasty are approved treatments for displaced femoral neck fractures, in the physiologically elderly, the most common treatment is to perform a hemiarthroplasty. Performing a hemiarthroplasty rather than a total hip arthroplasty in our defined patient population may put the patient at a higher risk for morbidity and future complications. It has been noted that patients undergoing hemiarthroplasty for fracture of the hip can indeed experience compromised function and, over the long term, the hemiarthroplasty will lead to destruction of the articulating acetabular cartilage, often resulting in the development of debilitating hip pain<sup>7-9</sup>. However, in a select group of hip fracture patients who have concurrent osteoarthritis or rheumatoid arthritis, a total hip arthroplasty has been the treatment of choice. Such patients have performed well after surgery, demonstrating improved functional hip scores and activity levels<sup>10-12</sup>. Often, but not always, THA has been avoided in patients without prior hip disease and pain due to fears of dislocations. In light of possibly enhanced function following THA, the question now is whether there is a role for a total hip arthroplasty, rather than hemiarthroplasty, in ambulatory patients with displaced femoral neck fractures, even if the patient has a "normal" articular surface at the time of the fracture.

Although the results of the previous studies are promising, there is still no definitive answer and the treatment norm has not changed. Because our study will use the current technology, limit our patient population to a well-defined group, and have the power of a prospective randomized study we could offer the definitive answer and with that change the norm of treatment.

Hypothesis:

- (1) Total hip arthroplasty will result in significantly superior functional outcomes at 12 and 24 months for non-institutionalized hip fracture patients, as assessed by valid and reliable measures of functional status.
- (2) The rates of reoperation (from any cause) at 24 months following surgery in patients receiving total hip arthroplasty will be lower than those in patients undergoing hemiarthroplasty.

## B. Study Design and Statistical Analysis

### a. Design

This project is a multi-center randomized controlled trial of the efficacy of total hip arthroplasty versus hemiarthroplasty in Garden III and IV displaced femoral neck fractures in physically active, non-

institutionalized hip fracture patients who are without concurrent hip disease 50 years of age and older. Fifteen US sites with adequate hip fracture case loads will be recruited to take part in this multi-center study and each site will attempt to enroll 20 to 30 patients during the 12 month enrollment period. Each site will have its primary investigator and other co-investigators, all of whom agree to enroll patients in the study and strictly adhere to randomization protocol. Patient will then be followed for a period of 24 months following surgery, utilizing regular office visits

#### **b. Outcomes**

Over the ensuing 6 months (to one year) follow-up patients will continue to demonstrate a slow improvement. Formal orthopaedic postoperative evaluations are performed on patients at 1, 3, 6, 12, 18, 24, and 36 months post discharge including symptom assessment, physical examination and hip x-rays. For the purposes of the study, these routine hospital visits will be utilized to perform medical evaluations as well as assessments of functioning on all participating patients at 6, 12, and 24 months post discharge.

**Primary Outcome Measurement:** The Timed Up and Go Test (TUG) is a test of balance that is commonly used to examine functional mobility in community-dwelling, frail older adults. The test requires an adult to stand up, walk 3 m (10 ft), turn, walk back, and sit down. Time taken to complete the test is strongly correlated to level of functional mobility and has a high degree of inter- and intra-rater validity (.80-.96, and <sup>13</sup>. This test will be conducted at the 6, 12 and 24 month visits.

**Secondary Outcome Measurement:** The Medical Outcomes Study (MOS) 36-Item Short Form (SF-36) Health Survey questionnaire is a measure of health status that measures eight dimensions of health: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, general mental health, social functioning, energy/fatigue, and general health perceptions. In addition, it also contains a single item which measures self-reported perceived change in health. Reliability has been estimated for all of the SF-36 scales to be 0.78 or higher. Of the eight domains in the SF-36, three - physical functioning, social functioning, and physical role function - have been selected as being most appropriate and probably maximally responsive in the post-THA setting.

#### **c. Statistical Analysis**

From prior studies in the elderly orthopedic population, we conservatively estimate the standard deviation of the TUG scores to be 15 seconds.<sup>14, 15</sup> We would like to detect a mean difference of 5 seconds in the Timed "Up & Go" Test between the hemiarthroplasty group and the THA group, as we feel this would be a significant clinical difference in the outcomes of these two surgeries. This would require a sample size of 143 person per group while maintaining a power of .8 and an alpha of .05. To accomplish this, we will recruit 400 patients (~25-30 per site) for randomization following a Garden III or IV femoral neck fracture to receive either a hemiarthroplasty or a total hip replacement. With an estimated mortality and/or dropout rate of ~20% in the 24 months following surgery, we anticipate having >150 persons in each arm of the study at 24 months.

### **C. Study Procedure**

Historical information obtained will include basic demographic data (age, education, gender, income, race), identification of an independent observer (family member, friend or other primary contact person with whom the patient has regular interaction or from whom the patient receives care). The presence and severity of comorbid diseases such as ischemic heart disease, congestive heart failure, valvular heart disease, hypertension, cerebrovascular disease, neurologic disease, chronic obstructive lung disease, asthma, peripheral vascular disease, coagulopathy, deep venous thrombosis, pulmonary embolism, psychiatric conditions, autoimmune disease, and cancer will be documented. The patient's

history of smoking and alcohol use will be determined. The history of falling and fall-related injuries will also be obtained. The patient's current medication use in the last 3 months will be documented

A standardized physical examination will be performed and documented pre-operatively. This examination will include height, weight, vital signs, pulmonary, cardiovascular, and neurologic examination. Baseline laboratory data will be recorded. In addition, standard antero-posterior films of the pelvis and hips are routinely obtained. The type and severity of the hip fracture will be characterized by the Garden system for femoral neck fractures, as defined above.

Eligible patients will be randomized either to a hemiarthroplasty arm or to a total hip arthroplasty arm of the study. We will use a central computerized, call-in, block randomization for each of the sites to ensure no investigator gaming of the randomization. Surgeons may choose their implant of choice within the class of hemiarthroplasty implants or THA implants.

All post-operative care will be standardized and will be similar for both groups of patients. Patients are encouraged to dangle their feet within 24-hours and to ambulate thereafter. Minimal length of stay is 3 days.

For the first 6 weeks post-discharge, patients continue to perform lower-extremity exercises under the supervision of the physical therapist twice a week for 30-minute sessions. Home health aides are provided on an individual-need basis, with approximately 75% of patients being discharged with a home health aid. For all patient recovering from a hip fracture requiring surgery, the Visiting Nurse Service also makes a 6-week assessment regarding the need for further physical therapy. From 6 weeks until 6 months, walkers (if used) are gradually replaced by a cane so that by 6 months most of the patients are either independent in terms of ambulating or require only a cane. By 6 months the visiting nurse and the physical therapist services are discontinued with the patient maintaining their own physical therapy.

Over the ensuing 6 months (to one year) follow-up patients will continue to demonstrate a slow improvement. Formal orthopaedic postoperative evaluations are performed on patients at 1, 3, 6, 12, 18, 24, and 36 months post discharge including symptom assessment, physical examination and hip x-ray. For the purposes of the study, these routine hospital visits will be utilized to perform medical evaluations as well as assessments of functioning on all participating patients at 6, 12, 18, and 24 months post discharge. At these visits, patients will be asked to complete the SF-36 forms. For patients with poor eyesite, the site study coordinator or the office nurses assistant will help the patient to complete the forms. This person will not have looked into the patients file to see which type of surgery the patient has had. Then the patient will be tested with the Timed "Up & Go" by the same person, allowing for one trial run before the test is time and recorded

#### **D. Study Drugs**

No drugs will be used in this study beyond what is normally administered pre-operatively for pain control, and immediately post-op for adequate pain control and DVT prophylaxis.

#### **E. Medical Device**

Specific investigators will choose their implants (cemented or cementless; modular unipolar or modular bipolar; various models of total hip prostheses). Monoblock endoprostheses will not be used. The operative approach used will be either an anterolateral or posterior approach with soft tissue repair. Trochanteric osteotomy will not be used. Patients will be randomized to one or the other arm of the study prior to surgery.

#### **F. Study Questionnaire**

The 36-Item Short Form (SF-36) will be provided to the patient at the 6, 12 and 24 month visits (in Spanish if the patients prefers). Specifically, three of the measures (physical functioning, social

functioning, and physical role function) will be assessed in this population as they will most likely be maximally responsive in the post-THA setting

## **G. Study Subjects**

### **a. Inclusion criteria**

- (1) Patients admitted with Garden III and IV displaced femoral neck fractures, defined as follows: Garden III - The distal fragment is rotated laterally. The proximal fragment is tilted into varus and rotated medially. The medial trabeculae of the head are in alignment with those of the pelvis; Garden IV - The capital fragment is completely detached from the distal fragment and has returned to its normal position in the acetabulum; the medial trabeculae are not in alignment with those of the pelvis. The distal fragment is displaced upward and anterior to the proximal segment
- (2) Age greater than or equal to 50 years. The age cutoff has been selected because in patients less than 50 years of age an open reduction and internal fixation is the treatment of choice for Garden III and IV type fractures.
- (3) Ambulatory individuals who are not residents of a nursing home. We have specifically chosen to study independent and physically active subjects because it is these patients that we hope can return to near-pre-fracture functional status.

### **b. Exclusion criteria**

- (1) Chronic dementia defined by a score of less than 21 on the Folstein Mini-Mental State Examination, a method for grading cognitive state. Patients with scores less than 21 will not be likely to follow commands for functional testing, comprehend the questions in measures of functional capacity and may not be able to give consent.
- (2) Patients with diagnosed renal osteodystrophy, osteomalacia, or pathologic fracture (i.e., malignancy). In patients with underlying concomitant comorbid conditions which predispose to severe osteopenia the outcome of surgery maybe significantly different.
- (3) Patients with ipsilateral femoral shaft fracture. Patients with ipsilateral femoral shaft fractures will be excluded because of the necessity of using alternative fixation techniques in these patients.
- (4) Patients with any fractures of the long bones in the lower extremity, fracture of the spine, and/or intra-thoracic or intra-abdominal injury (i.e., multiple trauma). Because the outcomes and clinical course of patients with multiple trauma may be quite different from a non-trauma patient, such subjects also have been excluded.
- (5) Patients with pre-existing significant arthritis. In patients with significant concomitant osteoarthritis in the hip (identified radiographically with subchondral sclerosis, cyst formation, osteophytes, or significant joint-space narrowing associated patient-reported pain), a total hip arthroplasty is indicated. In addition, patients with underlying inflammatory arthritis, such as rheumatoid arthritis, total hip arthroplasty may also be indicated; if not, the presence of multiple joint involvement in these illnesses may define a unique set of functional outcomes.
- (6) Patients who are unable to read or comprehend English or Spanish. Because validated functional status questionnaires are currently available only in English and Spanish version, we have limited our eligible subjects to those individuals who are conversant in either or both English and Spanish.
- (7) Patients and physicians who refuse to participate in the study. Prior experience suggests that this number will be about 10%.

**H. Study Recruitment**

The consulting surgeon will identify potentially eligible patients at the time of the patient's admission to the hospital with a displaced femoral neck fracture. The patient will then be entered into the subject log. If the patient has a Garden III or IV femoral neck fracture, agrees to have surgery and meets the inclusion/exclusion criteria (this will include a test of cognitive state), the surgeon will approach the patient about study involvement. All patients who are willing to participate and meet the inclusion criteria will then be asked to provide written consent to be randomized to one of the arms of the study. Once a patient agrees to participate in the study, the surgeon or study research coordinator will obtain study consent.

**I. Confidentiality of Study Data**

All data will be coded by study ID number for analysis, with the study coordinator having the only link to patient name and chart number

**J. Potential Conflict of Interest**

Because all orthopedic prosthesis companies make both hemiarthroplasty prostheses as well as total hip implants, there should not be a conflict in interest for surgeons using one device over the other.

**K. Location of the Study**

The study will be conducted at CUMC (including the Allen Pavillian), as well as 14 other yet-to-be determined centers that can guarantee adequate patient enrollment based on current femoral neck fracture case loads and physician willingness to participate in this study.

**L. Potential Risks**

Both surgical implants are currently accepted treatment options, however, there is a possible increased risk of dislocation using a total hip implant (necessitating manual or even surgical reduction), while the risk of reoperation with a hemiarthroplasty if the patient is extremely active may be increased

**M. Potential Benefits**

For the particularly active older patient, the benefit of receiving a total hip replacement

**N. Alternative Therapies**

Currently the only accepted treatments for a displaced femoral neck fracture in older adults (>50) is a hemiarthroplasty or THA. Conservative treatment and nailing or external screw placement has a very high rate of non-union and avascular necrosis of the femoral head, leading to very poor outcomes.

**O. Compensation to the Subjects**

There will be no compensation provided to the study subjects.

**P. Costs to Subjects**

There will be no additional cost to subjects as all information gathered by the study occurs during normal post-operative care and follow-up.

**Q. Minors as Research Subjects**

No minors will be enrolled in this study.

**R. Radiation or Radioactive Substances**

Patients will incur no additional radiation than the standard x-rays (AP and lateral pelvis, and/or frog-leg views) used to initially access a hip fracture, ensure correct alignment immediately post-op, and to track prosthesis orientation at follow-up at 1, 3, 6, 12, and 24 months.

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