The ROBODOC Clinical Trial: A Robotic Assistant for Total Hip Arthroplasty

Evelyn Harkins Spencer

Operating room teams at three U.S. hospitals are participating in a controlled clinical trial to evaluate the use of a surgical robot in total hip arthroplasty. The robot, called the ROBODOC Surgical Assistant System, precisely prepares the femoral canal for the placement of a "press fit" cementless prosthesis. The Food and Drug Administration (FDA) requires that the robot, as an investigational device, be tested in a controlled clinical trial to demonstrate safety and efficacy. The clinical trial will include 300 patients who must meet specific criteria before enrollment and randomization. This article describes the need for new surgical technology, ROBODOC's development history, hardware and software components of the system, the patient population and surgical protocol for the clinical trial, special nursing care requirements, and considerations for patient rehabilitation.

Evelyn Harkins Spencer, MSN, CRNP, C, is Coordinator for the Total Joint Registry Center for Orthopaedic Research at Shadyside Hospital in Pittsburgh, Pennsylvania.

Approximately 230,000 total hip replacements are performed annually in the United States (Graves, 1990). Incapacitating pain, often associated with end-stage osteoarthritis, is the most common indication for this treatment. Arthritic patients are plagued with pain, sleep disturbances, and limited mobility problems that drastically restrict daily activities and cause emotional distress. Fortunately, total hip arthroplasty can significantly improve quality of life for most of these patients (Wiklund & Romanus, 1991).

Evolution of Surgical Techniques for Total Hip Arthroplasty

Cemented Total Hip Arthroplasty

During the 1960s and 1970s, cemented total hip arthroplasty was the treatment of choice for osteoarthritic hips, despite patient age, weight, or activity level. In this procedure, bone cement secures the prosthesis within the femoral canal and covers irregularities and rough surfaces. However, during the 1980s, the incidence of failure at the cement-bone interface and loosening of the femoral component in patients younger than 50 years old ranged from 4% to 21% within 4 to 6 years in three clinical studies (Wilson & Poss, 1992).

Cementless Total Hip Arthroplasty

Porous-coated prostheses were developed to provide an alternative to cemented implants. These prostheses achieve biologic fixation when bone grows into the porous coating. Investigators report a 2% revision rate at 30 months follow-up due to femoral loosening and Harris hip scores greater than 90 (Wilson & Poss, 1992). A Harris hip score of 90-100 is considered an excellent result, 80-89 a good result, 70-79 a fair result, and less than 70, a poor result (Harris, 1969). Harris and Sledge (1990) report revision rates of only 4% over the first 5 years for cementless femoral components. However, thigh pain believed to be associated with inadequate fixation in the femur has been reported in 3% to 19% of cases (Wilson & Poss, 1992).

Precise fit of the implant increases bone-to-implant contact, providing stress transfer from prosthesis to bone and more bone growth into the prosthesis. Paul, one of the robot developers, states, "The classic technique of preparing the femoral canal for cementless implantation is inherently imprecise: using handheld reamers and mallet-driven broaches, the orthopaedist relies on experience and 'surgical feel' to create the cavity" (Paul et al., 1992, p. 2).

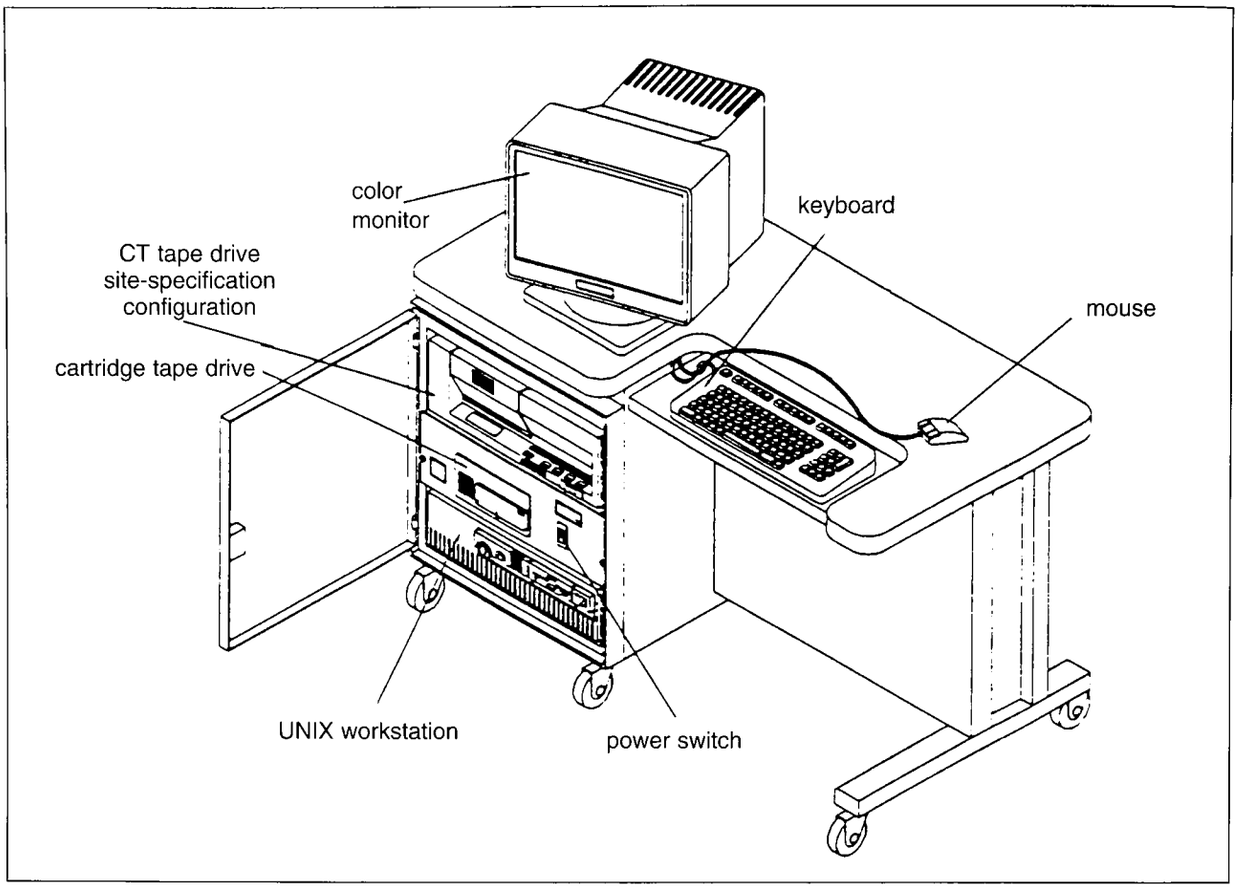

Figure 1. The ORTHODOC workstation.

Studies show that gaps between the cementless prosthesis and the bone cause *micromotion* and negatively affect both the quantity and quality of bone growth into the surface of the prosthesis (Paul et al., 1992). Micromotion of the implant in the femur is also believed to be the cause of thigh pain associated with cementless implants. Furthermore, manual broaching stresses the bone, and intraoperative fracture of the femur is a significant clinical complication (Bargar & Carbone, 1993).

The ROBODOC Surgical Assistant System

The need for better femoral canal preparation prompted researchers in 1986 to explore the feasibility of using a robot to mill the canal. The ROBODOC developers believe that robotics will provide consistent results and enable surgeons to follow their preoperative plans for shaping, sizing, and positioning femoral canals for selected prostheses.

Development of a prototype robot began at the University of California at Davis as a joint venture between researchers at the university and IBM. The prototype was first used in laboratory experiments and then in a canine clinical trial in 1989. The accuracy with which the prototype could mill a cavity and its efficacy in the canine trial convinced the researchers that robotics was a feasible technology for femoral canal preparation.

With initial funding from IBM, the researchers founded Integrated Surgical Systems, Inc., in 1990, and the company developed the present system in use at the clinical trial sites. These sites are Sutter General Hospital in Sacramento, New England Baptist Hospital in Boston, and Shadyside Hospital in Pittsburgh.

The ROBODOC system includes a computer workstation that simultaneously displays computerized tomography (CT) images of the patient's femur and a selected prosthesis. By manipulating these three-dimensional computerized images, the surgeon can graphically determine how the implant should be positioned with respect to anteversion, retroversion, varus, valgus, and leg length. The surgeon is also able to view sagittal, coronal, transverse, and zoom views, as well as a three-dimensional model of the femur and the prosthesis. Expected clinical benefits include fewer femoral fractures; complete bony ingrowth, resulting in less thigh pain; implant loosening and revision surgery; and long-term fixation of the implant to bone (Bargar & Carbone, 1993).

Another potential economic benefit is accurate preselection of the prosthesis that allows for a smaller inventory of implants. Currently, data are being collected to determine whether the implants selected during preoperative planning match the implants used in both the robotic and control procedures.

The ROBODOC Surgical Assistant System consists of:

1. the ORTHODOC workstation that includes an RS/6000 computer with a large capacity disc drive, color monitor, keyboard, mouse, tape drive, tape cartridge unit, and UNIX computer operating system
2. a five-axis robot
3. the operating room display
4. the control cabinet.

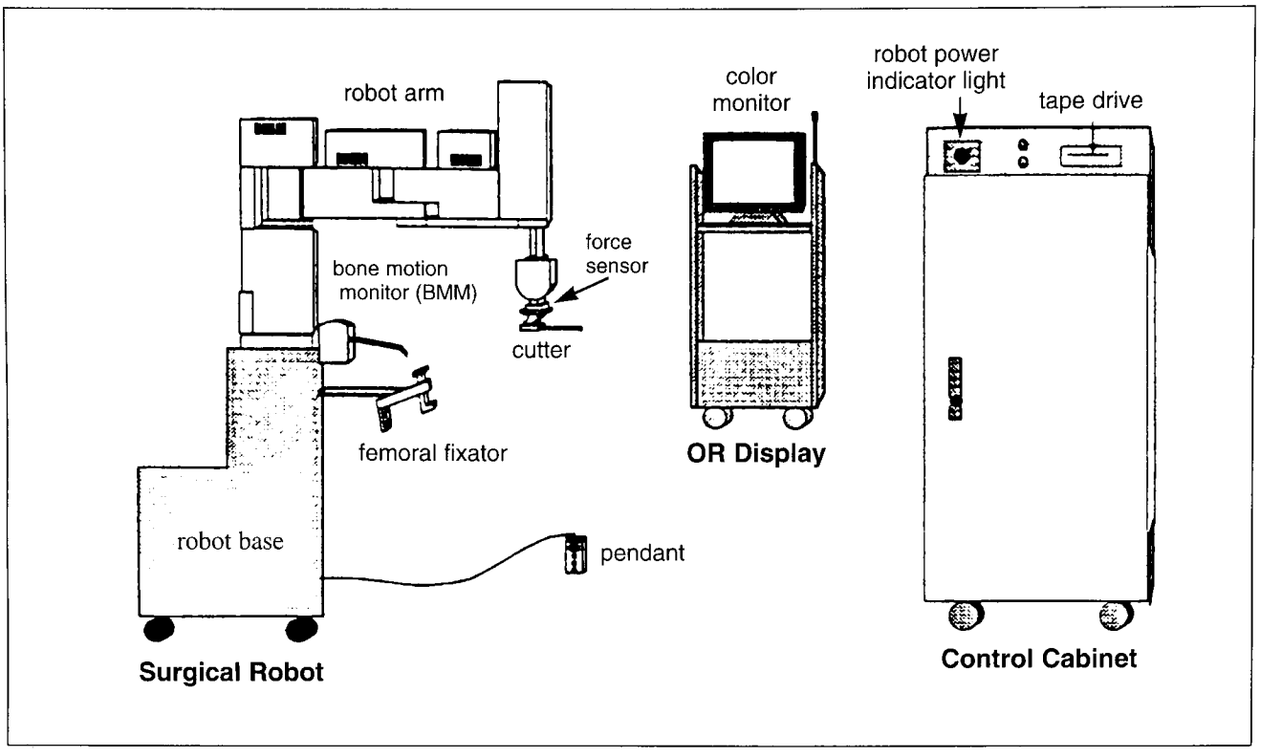

Figure 2. The ROBODOC Surgical Assistant has three components in the operating room: the surgical robot, the OR display, and the control cabinet.

Figure 1 illustrates the components of the ORTHODOC workstation. The operating room components of the ROBODOC Surgical Assistant System consist of the three physical units shown in Figure 2.

Patient Selection for Cementless Implants and ROBODOC Clinical Trials

Cementless implants have gained widespread acceptance for patients who place high demands on bone cement and are prone to loosen their prostheses. These patients are usually young or middle-aged, physically active, or overweight. Although these patients may be ideal candidates, to evaluate the efficacy of the ROBODOC Surgical Assistant System across the population, the clinical trial is not limited to patients meeting these criteria.

In addition to meeting the standard criteria for traditional cementless total hip replacement surgery, the 300 patients who participate in the ROBODOC clinical trial must meet the following criteria:

- The patient needs a primary total hip replacement due to painful arthritis or avascular necrosis.
- The patient is between 21 and 80 years of age.
- The patient does not have a condition that would reduce the ability of the bone to withstand the stress required for preparation of the femoral canal and proper implantation of the cementless femoral prosthesis (e.g., severe osteoporosis, Paget disease, renal osteodystrophy).
- The patient does not have a systemic illness that would render him/her unable to perform appropriate postoperative rehabilitation or be unable to render adequate assessment of pain and/or gait.
- The patient has no physical impairments or plans for elective orthopaedic surgery (other than primary total hip arthroplasty of the contralateral hip) that would impede rehabilitation or preclude adequate assessment of pain and/or gait.
- The patient has no metallic implants in the operative hip joint and/or ipsilateral limb.
- The patient is mentally capable of complying with the requirements of preoperative and postoperative care.
- The patient is able and willing to comply with postoperative follow-up for 2 years at one of the clinical sites.
- The patient is willing to accept randomized assignment into the study.

Protocol for ROBODOC Surgeries

Preoperative Procedures

To prepare a patient for a ROBODOC surgery, the surgeon must first implant three titanium locator pins, one in the greater trochanter and one on each condyle of the distal femur. These locator pins are actually screws. The proximal greater trochanter pin measures 4.5 x 10 mm, and the distal femoral condyle pins measure 6.5 x 15 mm. The surgeon makes a small incision and exposes the bone surface for placement of the pins in the bone. The pins are advanced until the heads are flush to the bone surface, and the incision is closed.

During the procedure, fluoroscopy is commonly used to confirm accurate placement of the pins as shown in Figures 3 and 4. This procedure is usually performed under general anesthesia as an outpatient procedure. For purposes of the clinical trial, pin placement must occur either within 24 hours or 7 days or more before the robotic total

Figure 3. This fluoroscopic anterior/posterior x-ray view shows the locator pins in the greater trochanter.

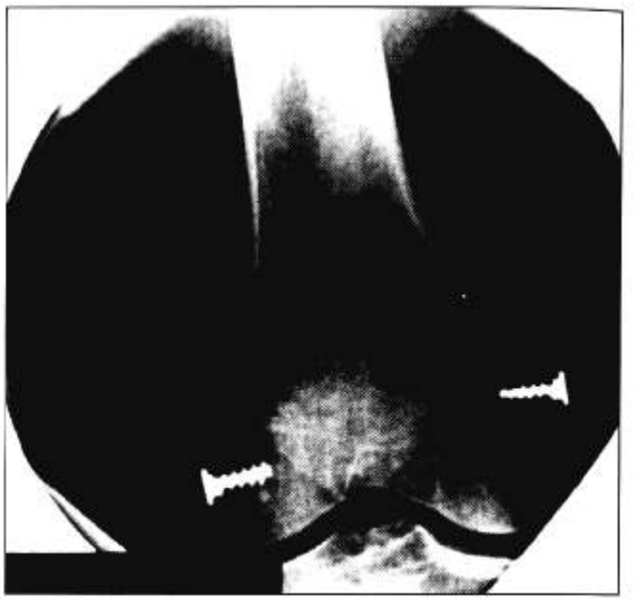

Figure 4. This fluoroscopic anterior/posterior view shows the locator pins in the medial and lateral distal femoral condyles.

hip arthroplasty procedure. The rationales for these timeframes are that within 24 hours there is little time for an infection to develop at the pin sites. Similarly, the 7-day or longer period allows time for the tissues to heal, and for signs and symptoms to become manifest, if infection is present.

The purpose of the pins is for registration. Registration is the process of enabling the robot to find points of location from the CT data of the femur, and to correspond these points to the actual femur in the operating room. The pins are markers that enable the robot to register the location of the bone in space.

After the pins are implanted, a CT scan is taken to obtain three-dimensional images of the patient's femur. To assure that there is no motion during the CT scan, the patient's legs are secured in an immobilizer, and an aluminum bone motion rod is taped to the leg to be scanned. The CT scan data are stored on a magnetic tape and loaded into the ORTHODOC workstation for validation and preoperative planning. A trained technician confirms that there was no motion of the alumimun rod during the CT scan by a computerized validation of the tape.

The surgeon manipulates these images to select an appropriate prosthesis and then positions it in the desired location within the femoral canal. Figure 5 is a photograph of the screen display of preoperative planning on ORTHODOC. When the prosthesis appears to be properly positioned, the surgeon saves the preoperative plan on a tape for later use as input to the robot in the operating room.

Figure 5. The ORTHODOC workstation has four quadrants that display images of the patient's femur, the prosthesis, and the bone motion rod.

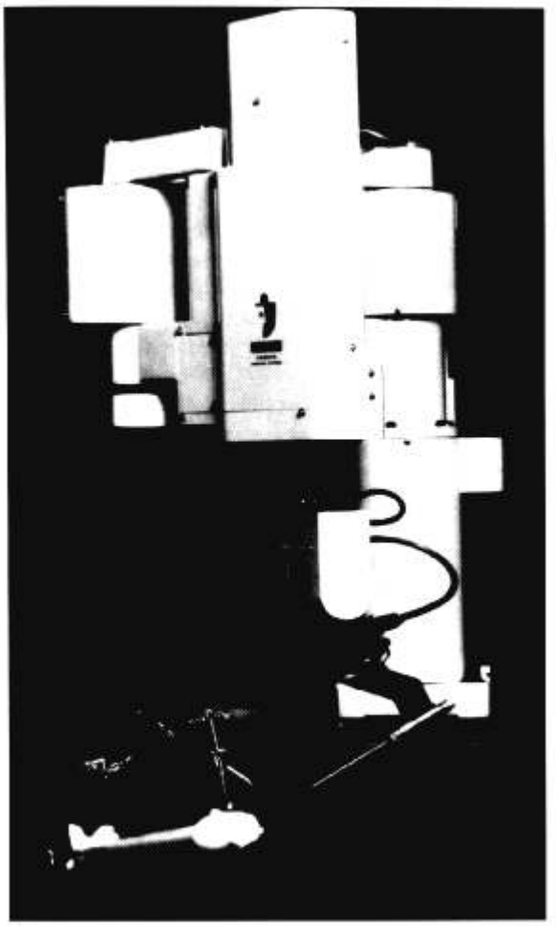

Figure 6. The Surgical Robot with a foam femur in the fixator and ball probe.

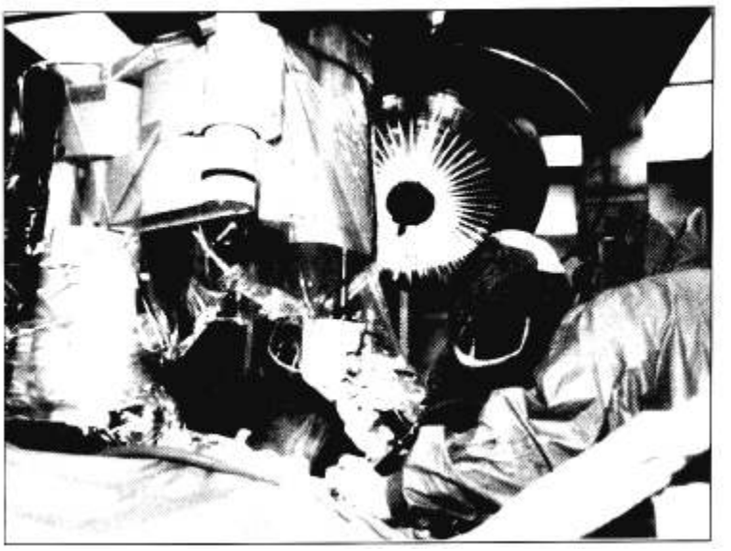

Figure 7. This photograph shows the Surgical Robot in use during an actual surgery.

Robot Preparation

Before each surgery, the technician calibrates the robot and conducts a series of diagnostic tests to ensure that the robot is functioning properly. The robot base and most of the arm are covered with a sterile drape, and the sterile cutter drive assembly is attached.

Surgical Protocol

The surgeon begins the operation in the traditional manner by exposing the joint capsule, dislocating the hip, performing a femoral head osteotomy, and placing the acetabular cup. The surgeon then exposes the locator pins and installs a fixation device on the femur that attaches to the robot base to prevent the femur from moving during robotic milling. The robot and femoral fixator are shown in Figure 6. When the femur is secure, the surgeon installs a ball probe in the robot's end effector and guides the probe to register the location of the three locator pins.

The robot computes the actual pin positions relative to the coordinates in the CT data and uses these computations to determine how the bone is oriented and where the cavity should be positioned. The resulting computations guide the cutting tool during femoral preparation (Bargar & Carbone, 1993). After leading the probe to the locator pins, the surgeon replaces the probe with a cutting tool and the robot machines the cavity for the femoral component of the prosthesis.

During the femoral milling, the surgeon irrigates the canal and views the progress of the milling on the operating room monitor that displays the cutting path. The surgeon controls the robot by a hand-held sterile pendant, or mouse. The surgeon can stop the robot at any time during the procedure. The femoral milling takes about 20 to 50 minutes to complete. The surgeon then places the prosthesis, removes the femoral fixator and locator pins, closes the locator pin site incisions, and completes the procedure in the traditional manner. Figure 7 is a photograph taken during an actual robotic surgery.

If a technical problem arises with the ROBODOC Surgical Assistant System that cannot be resolved during the procedure, the robotic procedure must be abandoned. The robotic equipment is carefully disassembled, and the procedure is completed manually.

Risks Associated with ROBODOC Surgery

As with any major surgery, total hip replacement with or without the robot has serious risks and potential adverse effects. They include blood and bone loss, infection, dislocation, unequal leg lengths, anesthetic reactions, soft-tissue damage, nerve damage, blood clots, and possibly death.

Additional risks associated with the robot include bone cavity placement errors from robot malfunction; bone damage from high-speed cutting during surgery; additional soft tissue damage; and pain, infection, and scarring caused by locator pin implantation and femoral fixator installation. There is additional radiation exposure associated with the CT scan and fluoroscopy if used during the pin placement procedure.

However, the ROBODOC Surgical Assistant System has many safety features incorporated designed specifically to prevent these additional risks. For example, a bone motion monitor detects movement of the bone and femoral fixator frame and causes the robot to pause, to prevent bone cavity placement errors.

One significant risk associated with the robotic procedure is prolonged surgical time. Surgical time was calculated based on data from 129 subjects. The average surgical time for the ROBODOC

group was 266 minutes compared to 125 minutes for the control group ($p<.0001$).

Pain and swelling at the distal pin sites proximal to the knee, and the risk for infection are additinal risks related to the pins. The pin placement procedure and prolonged surgical and anesthesia times associated with the arthroplasty procedure also pose additional risks related to the pins.

The developers are currently designing a "pinless" technique for registration. Disclosure and implementation of the technique are pending patent. Pinless registration will eliminate the pin placement procedure and the associated risks and costs. However, elimination of the pins for registration will not eliminate the need for CT scanning. Efforts are also underway to decrease milling time. Reduced milling times will reduce surgical time..

Care of a ROBODOC Patient

Patient Education

Nurses should ensure that patients are aware of the risks associated with the procedure. While the likelihood of the more serious risks is relatively small, ROBODOC patients should expect knee pain and stiffness from the locator pins. They should be able to recognize signs of infection, including erythema, edema, and purulent drainage.

After the locator pins are implanted, patients are limited to a sedentary activity level and partial weight bearing with crutches. These precautions are taken to prevent any movement, damage, or dislodgement of the locator pins.

Since the surgical protocol currently uses the posterolateral approach, dislocation precautions include avoiding flexion in excess of 90 degrees and internal rotation and adduction of the affected hips, particularly during the first 12 weeks after surgery. Currently, a protocol and adaptation for the anterior approach are being developed.

Nursing Care

In general the nursing care of the patient is similar to caring for patients who have undergone traditional cementless total hip arthroplasties. The proximal greater trochanter pin site incision is extended for the surgical approach to the hip capsule. However, the locator pin and femoral fixator halo pin sites are additional surgical wounds, and they require attention.

Postoperatively, nurses need to monitor the pin sites for signs of infection such as erythema, purulent drainage, and excessive edema. These patients will have more soft tissue and bone pain secondary to these wounds. Medicating appropriately and guarding these areas from insult, particularly when turning and transferring the patient, will help to minimize the discomfort.

Rehabilitation

For about 12 weeks after total hip replacement, patients should use an assistive device for partial weight bearing. ROBODOC patients frequently experience knee pain, stiffness and swelling associated with the distal pin sites. Physical therapy will focus both on the hip and knee of the affected side, but knee symptoms typically persist for 6 to 12 weeks and may prolong postoperative rehabilitation.

Costs Associated with ROBODOC Surgery

The additional costs associated with the ROBODOC surgery vary among institutions. They include the costs of the pin placement procedure, such as the surgeon's fee, operating room charges, anesthesia fees, and possibly charges for the use of c-arm fluoroscopy, if used to confirm adequate placement of the locator pins. Other added costs include the CT scan and the generally longer surgery time. While this procedure is investigational, third party payers are only reimbursing at the rate of traditional total hip arthroplasty procedures.

Long-term Results and Surgical Outcomes

Although the added risks and costs associated with using the system may delay widespread acceptance, the ROBODOC developers and the surgeons performing the clinical trials expect the benefits to outweigh the drawbacks. These benefits include a significant reduction in femoral fractures, improved implant fit, less thigh pain and prosthetic loosening, fewer revision surgeries, and improved long-term fixation of implant to bone in young patients.

Considering the added costs, the most likely candidates for robotic total hip arthroplasty are patients at high risk for loosening, such as the young, active, and obese. Improved surgical outcomes will be necessary to justify costs.

The purpose of the clinical trial is to demonstrate that the robot can perform the femoral canal preparation safely and effectively. Follow-up data will be collected for 2 years after surgery. However, the outcomes at 10 years, when implants are more likely to fail, will be more significant.

Documentation of long-term outcomes will demonstrate whether robotic technology is preferable for this surgical application. Unfortunately, long-term outcomes are beyond the scope and purpose of this clinical trial. Individual centers and surgeons for the clinical trial will have to follow patients over time to determine long-term outcomes.

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