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SYMPOSIUM

MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY

DEVELOPMENT, EARLY RESULTS, AND A CRITICAL ANALYSIS*

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Introduction

Hip replacement with use of small incisions has been practiced selectively by a few practitioners for many years, but only in the last several years has so-called minimally invasive hip replacement been widely introduced to the majority of orthopaedic surgeons.

Minimally invasive hip replacement, in fact, is not a single type of surgery but rather is a family of operations designed to allow total hip replacement to be done through smaller incisions, potentially with less soft-tissue disruption. The three main methods involve acombination of a small incision and a posterior approach to the hip, a combination of a small incision and an anterior approach to the hip, or two small incisions performed with use of the Smith-Peterson interval for acetabular placement and the approach usually used for femoral intramedullary nailing for femoral component insertion. Minimally invasive total hip arthroplasty has created much controversy among orthopaedic surgeons and a great deal of publicity in the popular press. Advocates emphasize the potential for these methods to reduce soft tissue trauma and thereby reduce operative blood loss, postoperative pain, and hospitalization time; speed the postoperative recovery; and improve the cosmetic appearance of the surgical scar. Advocates view minimally invasive total hip arthroplasty as a logical extension of less invasive methods that have revolutionized other fields, such as arthroscopy, laparoscopic cholecystec-tomy, and cardiac surgery, just to name a few. Those with reservations about minimally invasive total hip replacement point out that conventional hip replacement already provides excellent

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pain relief, functional improvement, and durability with a low complication rate. Skeptics are concerned that minimally invasive procedures introduce new potential **problems** related to reduced visualization at the time of the operation, such as implant malposition, neurovascular **injury,** poor implant fixation, **or** compromised long-term results.

Advocates **of minimally** invasive methods believe **that** minimally invasive hip arthroplasty holds the promise of providing all of the benefits of modern **total** hip arthroplasty along with shorter recovery and faster rehabilitation. **This** redefinition of the goals AOL surgery appears to resonate with some patients.

An unavoidable part of the discussion surrounding minimally invasive total hip arthroplasty has been an emotional element. Advocates at times seem to suggest that minimally invasive total hip arthroplasty **is** the way of the future and that those who do not learn it will be left behind. On the other hand, those with reservations often criticize the hype, the lack of objective data demonstrating the **benefit** of the procedure, and the marketing aspects associated with minimally invasive operations.

Beyond the emotional element of the discussion, serious and important issues are at stake. Even those **with** reservations about changing an already successful procedure cannot deny the potential advantages of reduced soft-tissue trauma and possibly quicker recuperation with less cost. At the same time, enthusiasts must be concerned about **the** new risks that these procedures and their widespread introduction might bring to an **operation** that in its present form is already remarkably successful.

Ultimately, orthopaedic surgeons need to determine whether minimally invasive methods actually provide their touted benefits, and at what cost, in objectively performed studies. The potential benefits of a smaller incision and possibly somewhat quicker rehabilitation need to be balanced against the added operative difficulty, reduced visualization, possibly increased operating time, and the drawbacks of a new learning curve associated with minimally invasive methods. Then, orthopaedic surgeons and their patients need **to** weigh **the** benefits and the risks to determine whether, for an individual patient and an individual surgeon, minimally invasive methods are worth pursuing. This symposium brings together advocates for and those with reservations about minimally invasive total hip arthroplasty to provide preliminary information on the results of these procedures and also to provide measured consideration of this topic. □

SINGLE-INCISION MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY

BY LAWRENCE D. DORR, MD

The use of a single "mini-incision" is the most common minimally invasive surgical technique for hip replacement. Hither a posterior or an anterior approach can be used. An incision length of <10 cm has become the usual definition of a mini-incision, but some surgeons use 12 cm. My experience has been with a posterior approach, which I use because it avoids any incision of the gluteus medius muscle. With this posterior approach, an 8-cm incision is made in the gluteus maximus muscle, and the capsule, with the external rotators, is elevated as a single tissue flap, which is then repaired at the completion of the operation. This technique allows patients to be fully weight-bearing immediately after surgery and provides them with early control of the lower extremity to optimize early function.

Several questions have arisen as a result of the performance of total hip replacement with a single mini-incision: (1) is this operation as safe as one performed with a traditional incision with regard to the avoidance of neurovascu-lar injuries and dislocation? (2) Does the patient have more rapid relief of pain and improvement in function because there is less muscle injury? (3) Can the components be positioned as reliably as they are with the larger, traditional incision? The purpose of this study was to attempt to answer these questions with regard to a single posterior mini-incision.

Materials and Methods

Three hundred and ninety total hip replacements performed with use of posterior incisions of <12 cm have beendone since February 2001. The first sixty operations were done with standard hip instrumentation, which usually required a 10 to 12-cm incision. During this time, instrumentation that allowed the operation to be performed through incisions of 5 to 10 cm was developed (Fig. 1). These instruments had curvatures and an increased handle length designed to minimize skin trauma and yet provide optimal exposure for reproducible component placement. A curved reamer for acetabular preparation was developed.

Ninety patients (105 hips) had a single incision that averaged 8.2 cm (range, 6 to 10 cm). During this same time period, sixteen hips (15%) required an incision of > 10 cm. The average age of the ninety patients was sixty-four years (range, thirty-seven to eighty-five

I and forty-five men. The average body-mass index for these patients was 26.2] (range, 19 to 37). The duration of the I operation from the time of the incision to closure of the wound averaged sixty-four minutes (range, fifty to seventy-three minutes). All patients received an uncemented cup (Anatomic Porous Replacement; Centerpulse, Austin, Texas) and a proximally porous-coated anatomic uncemented stem (Anatomic Porous Replacement). The hospital stay averaged 4.1 days (range, three to nine days), with only two of the ninety patients attending a rehabilitation facility. I During hospitalization, the daily pain score for these patients averaged 3 on a scale of 10 (with 10 indicating maximum pain). Thirty-six patients (40%) went home walking with a cane. At six weeks, sixty of the ninety patients were I able to walk without an assistive device I and one-third was able to walk with use of one cane. The complications in this group included an infection in one patient and a transient sciatic nerve palsy that lasted one month in another patient.

These patients were treated with an anesthesia and postoperative pain I management protocol that evolved during the study. The purpose of the protocol, which we now use, is to increase the functional recovery of the patient by minimizing postoperative nausea andemesis and by increasing alertness for physical therapy. The basic tenet of this program is to avoid epidural or intravenous narcotics. One hour before surgery, 40 mg of Bextra (vaidecoxib; Pfizer, New York, New York) and 20 mg of OxyContin (oxycodone; Purdue Pharmaceuticals, Stamford, Connecticut) are adminstered orally. Intraopera-tively, anesthesia is performed with an epidural catheter with use of 8 to 10 mL of 1% ropivacaine (Naropin; AstraZen-eca, Wilmington, Delaware). The patient is kept unconscious during the operation with use of intravenous pro-pofol (Diprivan; AstraZeneca) with initial infusion of 200 ug/kg/min. This dose is then titrated to a maintenance level of 100 Lig/kg/min. No general anesthetic agents are used. Following the operation, in the recovery room, four hours after the initial dose of OxyContin, 20 mg of oral OxyContin is again given. On return to the floor, the patient is given 10 mg of Norco (hydrocodone; Watson Laboratories, Corona, California), one to two tablets every three hours, according to the age of the patient. The pain medicine is given preemptively throughout the first forty-eight hours. Ten to 20 mg of OxyContin is also given every twelve hours, if needed, to supplement the Norco. OxyContin has the tendency to make patients lethargic so it is avoided in favor of Norco whenever possible. Twenty milligrams of Bextra is also given every morning. Toradol (ketorolac; Roche Pharmaceuticals, Nutley, New Jersey) also can be used for "break-through pain." The patient is discharged home with 5 mg of hydrocodone, either Norco or Vicodin (Knoll Laboratories, Mount Olive, New Jersey), according to the individual's needs.

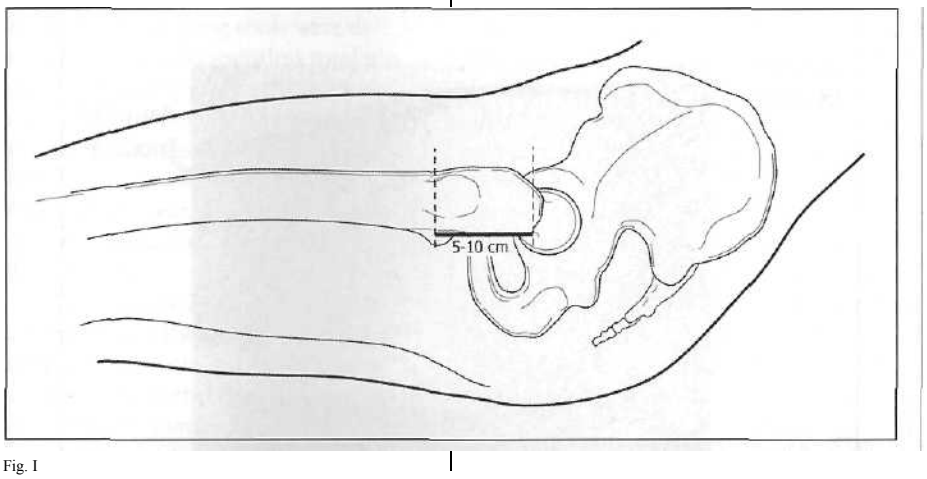

Fig. I

The position of the posterior incision is from the tip of the greater trochanter to the level of the vastus tubercle along the posterior border of the greater trochanter. This incision is placed at the posterior border of the greater trochanter and not over the surface of the greater trochanter.

Results

The radiographic results for these 105 hips showed that the average inclination angle (and standard deviation) was 38.4° ± 6.3° and the average anteversion was 20.1° ± 5.7°. The goal at the operation was an inclination of 25° to 45° and anteversion of 15° to 30°. Eleven percent the hips were outliers (those outside the desired range) with regard to inclination and 8% were outliners for anteversion. The femoral component alignment was within 3° of neutral in the coronal plane in ninety-five hips, 4° to 5° ofvarus alignment in nine hips, and 6° ofvarus in one hip in which a lateral femoral fracture (which subsequently healed without treatment) had occurred. The average limb length was increased 4.5 ± 4.8 mm compared with the preoperative length, and the average femoral displacement was increased 3.0 ± 6.2 mm. At two years after the operation, all femoral components were radiographically stable.

Gait analysis was performed for ten of the patients to gain an objective measurement of the functional recovery. Testing was done preoperatively and postoperatively. By ten weeks, the average gait velocity was 80% to 85% of normal, the average single-limb stance time was 90% of normal, the average cadence was 82% to 90% of normal, and the average stride length was 62% to 74% of normal (with the greatest deficit associated with hip extension). This level of function was reached sooner for the patients who had a mini-incision than it was for the patients who had traditional incisions, although the postoperative protocols were not identical.

Discussion

With our method and strict definitions of satisfactory component position, 11%

of the sockets fell outside the desired range of cup abduction and 8% fell outside the desired range of cup anteversion. Wenz et al. reported that, with their mini-incision, 7% of the cups were outliers, but they also accepted inclination of up to 55°, which is 10° above our accepted limit of 45°. We currently perform our minimally invasive operations with computer assistance in the hope that these outliers can be eliminated.

It is not possible to compare minimally invasive hip surgery with a single incision and that performed with two incisions because of the paucity of published data. Our experience with patients who are discharged home within twenty-four hours would suggest that the most important factors allowing early discharge include patient selection, patient motivation, anesthesia and pain management techniques, and the postoperative protocol rather than the use of one or two incisions. Even though we offer discharge home within twenty-four hours, few patients choose it. One of the greatest associated benefits of minimally invasive hip surgery for our patients has been the modification of anesthesia and pain management techniques to avoid epidural and intravenous narcotics because doing so nearly eliminates postoperative emesis and vertigo, which can interfere with in-hospital functional recovery.

The patients had good pain scores and functional recovery, but it has not been determined how much of the pain relief and functional recovery is attributable to new anesthesia and pain management techniques and to altered patient expectations and perceptions rather than to the operation itself. We have not yet answered the questions concerning the complication rate, pain level, or functional recovery associated with the mini-incision procedure compared with those associated with the traditional incision. □

NOTE: The author thanks Robin Chorn, MD, who helped to develop the anesthesia protocol described in this section.

DEVELOPMENT TWO-INCISION OF A MINIMALLY INVASIVE TOTAL HIP REPLACEMENT

BY DANA C. MEARS, MD, PHD

Early development of total hip arthroplasty and subsequent research efforts have focused on the identification of superior biomaterials that display better wear characteristics, strength, and fixation to bone to improve the implant durability. Although multiple surgical exposures were devised, each with an incision length of 6 to 12 in (15 to 30 cm) or more, they shared potential problems, all related to a prolonged weakness of the hip muscles, which manifest in a minority of patients as a limp or secondary instability of the hip joint. Innovations in other surgical specialties, such as en-doscopic cholecystectomy, were shown to reduce postoperative pain, shorten hospitalization, and accelerate clinical recovery. On the basis of these experiences, some surgeons began exploring the feasibility of performing total hip arthroplasty with smaller incisions and potentially less soft-tissue trauma. Different methods have been developed, and some of them use conventional operative approaches with progressively shorter incisions. My colleagues and I developed an approach using two small incisions to expose the acetabulum and the femur, respectively.

Development of a Two-Incision Surgical Approach

Our goal, as we worked in an anatomy laboratory, was to develop surgical routes to the hip without violating adja-

Intraoperative Verification of Stem & Cup Position

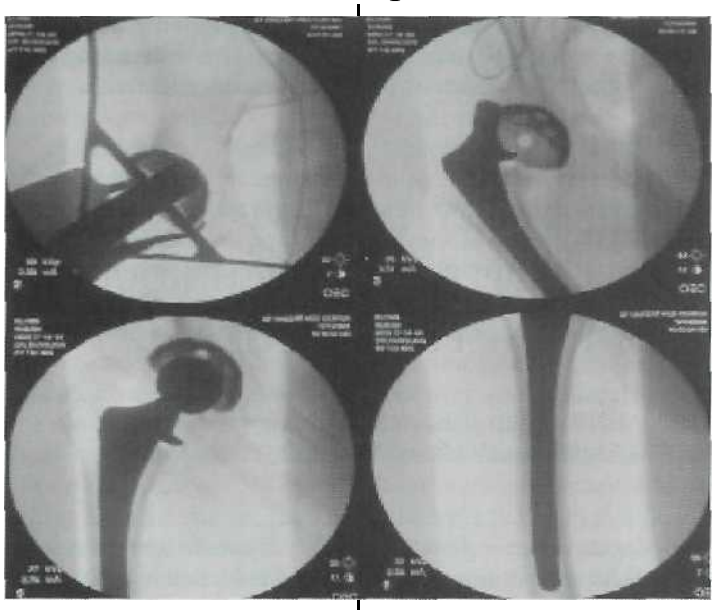

Fig. 3

Intraoperative fluoroscopic radiographs demonstrating (from top left, clockwise) cup **impaction,** the hip after implantation of the cup and the stem, the tip of the femoral stem, and the hip after reduction.

cent muscles **or neighboring** vessels and nerves. A **2-in** (5-cm) anterior incision was used to prepare the **acetabulum** and insert the cup. A second 1-in (2.5-cm) posterior incision was used to prepare the femur and insert the femoral component (Fig. 2). Special illuminated retractors and novel smaller handles for the bone-shaping tools were designed. Standard **cementless** total hip components of known efficacy were selected. Supplementary image intensification was used to provide intraop-erative **radiographic** guidance (Fig. 3). After a three-year developmental period, we filed a patent application for the method.

In January 2000, **a multicentei** clinical trial of the two-incision minimally invasive total hip replacement was initiated after receiving institutional review board approval. The study evaluated operative factors related to the procedure, such as operative time, blood loss, technical difficulty, and potential problems and complications. In addition, postoperative events in the hospital, as well as events after discharge, were examined.

Complications observed in the initial study included proximal femoral fractures, which occurred in 2.8% of the patients. This rate was about three times greater than that associated with conventional procedures. Other complications included partial, temporary injuries to the lateral femoral cutaneous nerve. Most of the femoral fractures occurred in a surgeon's first case and all occurred in the surgeons' first ten cases, as part of a so-called learning curve. In an effort to diminish the prevalence and clinical significance of the fractures, a proximally porous-coated device was replaced with a fully porous-coated femoral implant. As further clinical experience has been gained, we also have modified the orientation of the skin incision to allow a better view of the femur during preparation and have learned that extending the hip dining femoral preparation is helpful. These changes have made femoral preparation easier, may allow **a** wide selection of femoral implants to be used, and may reduce the risk of intraoperative femoral fracture.

Inlrnoperaiive Anesthetic Regimen and Postoperative Pain Management Historically, after a **total** hip replacement, a patient started physical therapy on the following day. Earlier initiation of therapy was hampered by the side effects of anesthetic agents and medications used for postoperative pain control. Problems with traditional perioperative regimens have included persistent pain, postoperative nausea, vomiting, urinary retention, drowsiness, confusion, muscle weakness, and numbness **in** the lower extremities. To optimize the potential of minimally invasive total hip replacement to allow rapid initiation of therapy and a corresponding acceleration in hospital discharge, we worked with Dr. Jacques Chelly to develop a regimen that reduced these undesirable features. The perioperative management regimen that we now use emphasizes regional anesthetics, use of non-narcotic pain medication, and portable local anesthetic infusion pumps to reduce pain.

We also developed an accelerated physical therapy program and clinical pathway that emphasizes immediate weight-bearing to tolerance and multi-ple physical therapy sessions for gait training and for teaching the activities of daily living in the first twenty-four hours after the operation. Recently, for patients with minimal comorbidities, this regimen has allowed over 90% of our patients to be discharged within twenty-four hours after surgery. Many patients have been able to shed all assis-tive devices within two to three weeks after hospital discharge.

Teaching Minimally Invasive Total Hip Replacement If future documental ion of the clinical outcomes after minimally invasive total hip replacement proves to be favorable, a major challenge will be to train orthopaedic surgeons to perform the surgical

Technique. During the past few years, industry-sponsored cadaveric courses have been established. Supplementary audiovisual presentations, visits to surgical procedures, and, potentially, a mentoring surgeon to assist in the first clinical procedure are available.

Whereas endoscopic training relied upon the availability of a highly comparable pig model, there is no such animal model for total hip replacement. To date, attempts to develop accurate plastic replicas have been disappointing. At present, few orthopaedic residencies possess a trained surgeon to educate their residents in the technique. I believe that surgeons need to gain specialized hands-on training in cadavera and by visiting experienced mentoring surgeons before undertaking these procedures independently. Q

TWO-INCISION MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY: OPERATIVE TECHNIQUE AND EARLY RESULTS FROM FOUR CENTERS

BY PAUL J. DUWELIUS, MD, RICHARD A. BERGER, MD, MARK A. HARTZBAND, MD, AND DANA C. MEARS, MD, PHD

Technique

One minimally invasive two-incision total hip arthroplasty approach involves the placement of an anterior incision that is 4 to 6 cm in length directly over the femoral neck. The skin incision is oblique from the intertrochanteric line to the center of the femoral head. The landmarks for the skin incision arc verified with fluoroscopy. The interval between the sartorius and the tensor fasciae latae is exposed superficially. The deeper interval utilizes the plane between the rectus femoris and the tensor fasciae la-tae. The anterior circumflex femoral vessels, which serve as a landmark for the anterior approach just superficial to the hip capsule, are ligated. The hip capsule is divided longitudinally from the center of the femoral head to the trochanieric ridge. The capsule is retracted with lighted retractors to allow for osteotomy of the femoral neck. The neck is osteotomized, and the femoral head and neck are removed in **situ.** Next, the lighted retractors are re-positioned to retract the capsule. An additional retractor maybe placed to retract the rectus femoris and allow for acetabular preparation. The acetabular labrum is removed with sharp dissection. The acetabulum is prepared by reaming with specialized beveled reamers, and the cup is inserted with 20° of anteversion and 45° of abduction. A specialized dog-leg cup inserter allows for proper acetabular cup position and avoids impingement on the femur. Screws may be inserted through the cup in the superolateral weight-bearing dome. The liner is then inserted. The cup position is verified with fluoroscopy.

A second, posterior, incision that is 3 to 4 cm in length is made in line with the femoral canal. The gluteus fascia is split superficially, allowing placement of reamers to prepare the femoral canal. A direct pathway to the femoral canal is found with blunt dissection posterior to the abductor tendons, anterior to the piri-formis tendon. Specially designed reamers are utilized to prepare the proximal part of the canal and to clean **out** the medial greater trochantcric region to allow for proper stem insertion. Anteversion is determined under direct vision by viewing the rasp through the anterior incision or by sighting the broach handle **off the** center of the patellae as an indirect landmark. Once the canal is reamed with straight reamers and the broaching is completed, **the** stem is inserted through the posterior incision. Either a proximally coated or a fully porous-coated stem can be used. Final seating of the stem can be seen under direct vision through the anterior incision. Fluoroscopy to confirm instrument position can be used at any time during the canal preparation.

Once the femoral stem is inserted, a trial reduction is performed. Because the patient is supine, the limb length can be determined by comparison with the contralateral lower limb. Hip stability is assessed by placing the involved limb through a full range of motion. After final prosthetic head placement, both wounds are closed. The anterior wound is closed over a drain.

Postoperatively, patients are managed with an accelerated critical pathway for total hip arthroplasty, in which they are seen by a physical therapist immediately upon return from the recovery room. Patients are allowed to bear weight as tolerated with crutches. Patients are discharged when they have met the critical pathway objectives.

Results

At one center (St. Vincent Hospital and Medical Center, Portland, Oregon), 100 patients under the care of Dr. Paul Duwelius were selected for the two-incision approach. Informed patient consent was obtained with institutional review board protocol. During this same time-period, this surgeon treated 183 other patients with primary total hip arthroplasty. The patients who were chosen for a two-incision procedure weighed less than 220 lb (100 kg), they were less muscularly developed than patients who had

one incision, and they were less than seventy-five years old. They also had no major comorbidities, osteoporosis, or cognitive impairment, and they had had no prior operations on the ipsilateral hip. The first twenty-five patients who had a two-incision procedure were managed with a proximally porous-coated uncemented stem (Fiber Metal MidCoat; Zim-mer, Warsaw, Indiana). The remaining seventy-five patients were managed with an uncemented Beaded FullCoat prosthesis (Zimmer). All had an uncemented socket (Trilogy; Zimmer). The primary diagnosis was osteoarthritis for ninety-four patients, osteonecrosis for four patients, and rheumatoid arthritis for two patients. The average age was fifty-seven years for the men and sixty years for the women. The average weight was 184 lb for the men and 141 lb for the women. The average operating time was ninety minutes (range, eighty to 120 minutes). Ninety patients were discharged home within twenty-four hours, and ten were discharged on the second postoperative day.

Complications included two posterior hip dislocations, both of which were treated with closed reduction and use of a brace for six weeks. Neither patient has had a redislocation. One femoral component subsided and required revision because of loosening. One patient had a calcar fracture, which was treated with a cerclage wire and advancement of the fully coated stem. The fracture healed without incident. There were no readmissions for medical complications. At nine months postopera-tively, one patient who had a primary diagnosis of rheumatoid arthritis had an infection develop around the pros-thesis, which was probably due to he-matogenous infection from a lung abscess. The average Harris hip score improved from 52 points preoperatively to 90 points at one year postoperattvely.

At another center (Hackensack University Medical Center, Hackensack, New Jersey), 100 patients under the care of Dr. Mark Hartzband were selected for treatment with a two-incision protocol. (During this same time-period, this surgeon performed 337 other primary hip arthroplasties with different operative approaches.) Fifty-six patients were men, and forty-four were women. The men and the women both had an average age of fifty-six years. The average weight was 194 lb for the men and 148 lb for the women. The preoperative diagnosis was osteoarthritis for eighty patients, developmental hip dysplasia for nine, osteonecrosis for eight, and trauma for three. An uncemented socket (Trilogy) and an uncemented femoral component (Beaded FullCoat Plus; Zimmer) were used in each patient. The mean duration of follow-up was twelve months (range, three to eighteen months). Complications included two femoral fractures, one deep venous thrombosis, and one bowel obstruction. There were no revisions or hospital readmissions. The average duration of the operation in this series was sixty-two minutes (range, thirty-eight to 140 minutes). Seventy-seven patients were discharged within twenty-four hours after surgery.

Dr. Richard Berger reported that, at his center (Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois), 100 patients were selected for treatment with a two-incision protocol, During the same time-period, this surgeon performed 534 other total hip arthroplasties. The two-incision procedures were performed only as the first operative procedure of the day, which limited the number of patients. During the first part of the study, only the patients with straightforward anatomy were chosen; during the middle part of the study, more difficult cases including obese patients and patients with dysplasia were chosen; and, for the remainder of the study, patients who were representative of the surgeon's practice were chosen. There were seventy-five men and twenty-five women. The average age was fifty-five years (range, thirty to seventy-six years). The diagnosis was osteoarthritis in eighty-seven patients, developmental dysplasia of the hip in eight patients, and osteonecrosis in five. The average weight was 176 1b (range, 102 to 2651b). All patients were treated with an uncemented socket (Trilogy) and an unce-mented fully porous-coated stem (Beaded FullCoat). Complications included one calcar fracture, which was treated with a cerclage wire and advancement of the fully coated, beaded stem. There were no other complications or readmissions. The duration of the operation was between eighty and 120 minutes (average, 101 minutes). Of the last eighty-eight patients, seventy-five (85%) were managed in an outpatient setting with discharge on the same day as the total hip replacement. The patients followed a rigorous critical pathway that included use of a regional anesthetic, immediate weight-bearing, and physical therapy on the day of surgery. There were no readmissions for any reason. No patient had his or her procedure aborted or converted to a different procedure. As reported by Dr. Dana Mears, seventy-five consecutive patients at his hospital (University of Pittsburgh Medical Center-Shadyside Hospital, Pittsburgh, Pennsylvania) had a total hip arthroplasty performed with the two-incision approach and with use of a modified anterior incision that was superficial to the intertrochanteric ridge. Informed consent was obtained with institutional review board protocol. Three patients underwent a bilateral procedure, and two others had sequential arthroplasties. This consecutive series of patients represents all primary hip arthroplasties performed by this surgeon during this time-period. Following this series, he excluded from the two-incision protocol patients with retained obstructive femoral or acetabular hardware, bone deformity, or marked osteoporosis suitable for a cemented stem. A proximally coated femoral stem (Fiber Metal Taper; Zimmer) was used with a multi-holed cup (Harris-Galante-2; Zimmer). The primary diagnosis was osteoarthritis for sixty-three patients, posttraumatic arthritis for five, developmental hip dysplasia for four, and rheumatoid arthritis for three. The men were an average of fifty-eight years old (range, thirty-two to eighty-four years), and the women were an average of sixty-two years old (range, forty-three to eighty-two years). The men weighed an average of 229 lb (range, 155 to 315 lb), and the women weighed an average of 184 lb (range, 112

to 270 lb). All patients **but** one were discharged directly to their homes. Seven patients were discharged on the day of surgery, and fifty-eight were discharged within a day after surgery. Seven patients, including the three with a bilateral procedure, were discharged on the second postoperative day. Two patients, one of whom was transferred to a rehabilitation center, were discharged on the fourth day.

There were no readmissions for medical complications. Two hips had an undisplaced calcar fracture that was recognized after insertion of a tapered stem and was treated with a cerclage wire. The fractures healed uneventfully, without stem subsidence or loosening. One stem subsided 5 mm **but** was asymptomatic. Two hips had Grade-I heterotopic bone, according to the classification of Brooker et al. Two patients had partial femoral nerve palsies, which fully resolved within eight weeks after the procedures. Sixteen patients complained of hypoesthesia of the anterior part of the thigh, consistent with a partial injury to the lateral femoral cutaneous nerve of the thigh. Nine of them had a full recovery, and the seven others had partial resolution. The average operating time was eighty-five minutes (range, fifty-five to 125 minutes). The authors (P.J.D., R.A.B., M.A.H., and D.C.M.) believe that the benefit of a two-incision minimally invasive approach for total hip arthroplasty is not the size of the incision but is, instead, the limited surgical dissection that is required. This procedure is dependent on the technique and the instruments, and both continue to evolve. This procedure is clearly more difficult than either the mini-anterior or mini-posterior incisions. In our limited experience to date, the early perioperative complication rate has been acceptable. Additional experience and longer-term evaluation will be needed to rigorously compare the results of this procedure with those of total hip replacement performed with conventional approaches. □

SKEPTICAL PERSPECTIVES ON MINIMALLY INVASIVE TOTAL HIP ARTHROPLASTY

BY JOHN J. CALLAGHAN, MD

Total **hip** replacement has been performed in the United States for over three decades and in Europe for more than four decades. It is one of the most, if not the most, studied surgical procedure ever in medicine. Its efficacy in relieving the pain and functional limitations from end-stage arthritis of the hip has been documented. During this thirty to forty-year experience, investigators and surgeons have documented some of the complications and shortcomings of the procedure as well as some of the potential innovations, which through the test of time have ended up being "steps backwards." The potential benefits of the minimally invasive approach (i.e., the cosmetic appearance, quicker functional return, short length of stay, and fewer transfusions) have been outlined. If these goals can be accomplished while still addressing the major issues that confront orthopaedic surgeons who perform total hip replacement today, there may be a place for this enthusiasm. However, as described below, there are several reasons for skepticism as well as for concern about the approaches that have been implemented to encourage the widespread use of the minimally invasive approach.

What is the major problem with total hip arthroplasty today? From both an economic perspective, as well as from the perspective of the patient requiring a total hip arthroplasty, the need for additional surgery following the index procedure is of paramount concern. The revision rate in the United States is 18% to 20%, and unfortunately it is twice that of some other countries such as Sweden, where the rate is 8%. More data are arising to suggest that the volume of surgery performed at an institution, as well as the volume EOT surgery performed by an individual surgeon, is a major factor contributing to the revision rate. However, the practical reality is that more, not less, total hip replacements will be indicated in the aging and active population, as data have suggested that people will be living longer (and hence have an increased risk for the development of disabling hip arthritis) and the so-called baby-boomer generation is reaching the peak age for the onset of disabling hip arthritis. These replacements cannot all be done at centers that do over 500 to 1000 hip replacements a year. There will still be a huge need for surgeons who perform less than fifty hip replacements a year. Arthroplasties need to be performed with the fewest complications and with the least possible need for revision, as both are costly to the patient and to society. In addition, the increase in the rate of obesity in this country may prohibit more and more patients with disabling hip arthritis from being optimal candidates for a so-called minimally invasive procedure. Some proponents of the procedure recommend that minimally invasive techniques be performed in patients with a body-mass index of less than 30.

What are the major complications following total hip replacement that require revision? Failure of fixation, instability, and infection have been documented as the major causes of reoperation following total hip replacement. To minimize failure of fixation, implant-

bone interfaces must be optimally prepared. To minimize dislocation, components need to be positioned optimally, osseous impingement (including osteophytes) should be eliminated, and stability needs to be assessed. To minimize infection, tissue trauma needs to be minimized, as does the duration of the operation. Small incisions do not address these problems, and they could potentially increase each of them, especially in the hands of a surgeon who is less skilled or who is doing fewer procedures. Some enthusiasts of the minimally invasive procedure assert that combining minimally invasive procedures with computer-assisted surgery will allow the computer images to overcome the lack of visualization allowed by the incision to optimize the position of the components. This presents a tremendous risk for very little, if any, proven benefit.

Is the comparison of minimally invasive hip surgery with the conversion from knee arthrotomy to knee **arthroscopy** accurate? There are reasons why this argument may not hold. The short and long-term results of knee arthrotomy, unlike those of total hip replacement, were not optimal. In addition, it has been documented that visualization is actually better with arthroscopy. This claim has not and cannot be made for minimally invasive hip surgery. Minimally invasive hip surgery may turn out to be more akin to the endoscopic carpal tunnel release than to knee arthroscopy. Endoscopic carpal tunnel release was touted for its ability to provide a smaller scar and early return to work. The subsequent peer-reviewed publications demonstrated no long-term benefit. Today, questions have arisen as to whether the potential early return to work after the procedure was mostly perceptual (the surgeons' enthusiasm for the procedure and the patients' desire to please the surgeon). The major complications of carpal tunnel release, including nerve laceration and tendon injury, still occurred after experience was gained with the procedure. For these reasons, endoscopic carpal tunnel release, which initially gained enthusiasm and popularity, has been abandoned by the majority of hand surgeons. This skeptic questions whether the results achieved by a traditional joint replacement surgeon who selects the most motivated and fit patients, convinces those patients of the possibility of early discharge, and performs the standard incision with optimal preoperative, intraoperative, and postoperative anesthesia, pain management, and rehabilitation would not match the early re-sults or exceed the long-term results achieved by the surgeon who uses the minimally invasive approach.

Are there medical-legal liability issues associated with implementing the minimally invasive hip replacement approach? The argument has been stated that, since the patient has come to the surgeon desiring the technique, then he or she must understand that there is a learning curve that could involve the potential for complications, such as nerve palsy and component malposition. Legally, the surgeon should recognize that he or she probably will be judged by the same standards as the surgeon who uses conventional incisions. In addition, complications may not be as well understood by patients with extremely high expectations of the surgery.

Has the minimally invasive hip surgery movement been appropriately implemented? The Internet and advertisements have encouraged patients to seek new treatments before traditional peer review can be completed. This creates potential problems for both the surgeon and the patient. There are many examples of self-aggrandizing promotions of unique treatments outside the peer-reviewed system that have not held up in the scientific review process or have not withstood the test of time. Our medical profession has been designed for us to self-regulate. We have an obligation to educate the public and help them to interpret nonscientific premises and promotions. Developers of groundbreaking treatments for patient care are obligated to promote their ideas through the scientific peer review of their data, which can substantiate their enthusiasm. In the case of the minimally invasive approach to hip surgery, the promoters have rarely recognized the work of Keggi, as reported by Light in 1980, who described a similar minimally invasive approach for performing total hip replacement. Finally, if a treatment does prove to be an improvement, it should not be limited to a select group of surgeons. These premises are the basis for the respect that the public holds for the medical profession today.

It is the job of a skeptic to ask tough questions. This skeptic hopes that minimally invasive hip surgery enthusiasts prove him wrong for this skeptical stance. □

ETHICS OF INTRODUCTION OF NEW OPERATIVE PROCEDURES AND TECHNOLOGY

BY JAY R. LIEBFRMAN, MD

There is a general consensus that new technology and innovative surgical techniques can enhance patient outcomes. Minimally invasive hip surgery has sparked substantial interest in the orthopaedic community because patient outcomes may be improved in both the short and the long term and because patients believe that smaller incisions will lead to improved

results. Although orthopaedic surgeons are read/ to embrace new technological advances, four major questions need to be answered in order to enhance the development of a new technology or new surgical procedures and still protect patient safety: (1) Is the development of a new surgical procedure an experiment or an innovation? (2) What is the role of **industry** in establishing widespread use of new procedures? (3) How do we provide our patients with true informed consent? (4) Why are failed procedures rarely reported to the orthopaedic community?

*Innovation Compared **with** Experimentation* Surgical innovation is essential to improve the care of patients over time. The question is whether the safeguards associated with the *regulatory ethics paradigm* are necessary in every case? According to the regulatory ethics paradigm, any innovative surgical treatment needs to be placed into a protocol that has institutional review board approval in order to protect patient welfare. Proponents of this **philosophy** believe that any surgical innovation is really human experimentation and must be evaluated with use of rigorous scientific experimental protocols. Therefore, if there is no protocol approved by the institutional review board, then the application of a surgical innovation would not meet ethical standards.

However, in a provocative essay, Agich pointed out that the regulatory ethics paradigm may not be appropriate for the development of new surgical procedures. A potential problem with the regulatory ethics paradigm is that it may not be applicable in situations where present treatments either are not **optimal** or are ineffective. The development of surgical techniques requires fine-tuning, which makes use of institutional review board protocols **difficult** during the developmental phase. The development of a new surgical technique may require frequent adjustments related to the surgical approach, the design of new surgical instruments, and the identification of the appropriate patient population. It could be argued **that** the development of a new surgical approach for total hip arthroplasty (i.e., **a mini-incision** or two small incisions) is just **a** modification of a well-established procedure and therefore does not require institutional review board approval. Although protocols approved by the institutional review board may not be necessary during the initial development of some surgical procedures, informed consent and protection of the patient's welfare are still absolutely necessary. The surgical innovator must also realize that he or she may have a potential conflict of interest with the patient. The new technique may not be better than the standard procedure. Therefore, true informed consent is essential.

The failure to perform a clinical trial to determine whether a new procedure actually provides benefits to patients is the strongest argument for applying the regulatory ethics paradigm **in** all cases. In general, once the surgical technique has been refined, a randomized trial should be performed, otherwise the efficacy of the new procedure will not be established. The widespread use of a new technique should be delayed until the indications, pitfalls, and potential complications have been identified. Numerous surgical techniques have been adapted by the orthopaedic community before the outcomes have been established in either clinical trials or a prospective analysis. Some examples include the use of the **microfracture** technique and autologous **chondrocyte** transplantation to treat cartilage defects and the use of nonvascularized or vas-**cularized** bone grafts to treat osteonecrosis of the hip. The development of an institutional review board protocol to compare a minimally invasive **hip** ar-throplasty with a standard approach **or** different types of minimally invasive approaches should not be avoided because it is inconvenient.

Industry and Innovation

When a new technology or even a new surgical procedure is being developed, industry can play an important role. Industry has the infrastructure to support the development of a new technology. In addition, companies have the resources to make a new technology available to a wider group of orthopaedists. Many advances made in orthopaedic surgery over the past five decades have occurred as a result of excellent collaborations between orthopaedic surgeons and industrial partners. However, there are a number of concerns that must be considered or else surgeons risk providing inadequate protection for their patients. First, financial gain could be placed ahead of patient interest. A company may push for rapid entry into the marketplace with a new technology or technique in order to obtain a return on an investment. Companies may wish to avoid clinical trials to save resources, especially if the results are uncertain or if a trial is not required by the Food and Drug Administration. Second, manufacturers have started to market directly to the consumer to move the marketplace in a specific direction. This may lead to an inadvertent conflict of interest with patient interests. Advertisements may urge patients to seek physicians who use new devices or new surgical procedures even though better outcomes have not been established. Finally, **a** manufacturer may discourage the free flow of information between surgeons, especially to individuals who do not have a defined relationship with the company. This type of communication has been a critical element in fostering clinical advances in the past. Therefore, orthopaedic surgeons who are working as partners with industry to develop new surgical techniques or other new technology must be aware of the potential conflicts of interest related to financial gain and must provide appropriate informed consent **for** their patients in order to protect patient welfare.

*Learning New Procedures and **Obtaining** Informed Consent*

What is the best way for the surgeons to learn new procedures? What training is necessary to learn new procedures? The

answers to these questions obviously depend on the type of procedure and the surgeon's previous surgical experience. However, it is important that the surgeon have a frank discussion with the patient about the potential benefits and risks of a new procedure and the surgeon's experience with that procedure. Patients often assume that a new procedure will have a better outcome than an old procedure. A patient may also underestimate the risks associated with the new procedure, particularly if it is called a minimally invasive operation. Patients may not grasp that, although a "minimally invasive operation" has a smaller skin incision, the complications associated with that procedure may be equal to or even greater than the complication rate associated with a standard surgical procedure. In addition, the patients need to understand that they may not experience all of the benefits of a new procedure during the learning curve for a new surgical technique. Finally, surgeons must be sensitive to overmarketing a new procedure to try to enhance their practice. There is a natural tendency to oversell new technology, which can have a negative impact on the doctor-patient relationship and can erode the public's trust in physicians.

Innovative Failures A major problem within the orthopaedic community has been a failure to publish negative results that are associated with any new technology. There are many potential reasons why this has occurred on a chronic basis. First, surgeon innovators often move on to the next innovation once it is clear that a new technique or technology does not work. Second, there is potential damage to a surgeon's reputation and financial interests for reporting negative results. Third, surgeons may want to avoid conflicts with industrial partners who may be reluctant to publish negative outcomes, particularly if the new technology is still being sold. Fourth, it is often quite difficult to publish negative data. However, the release of both positive and negative outcomes related to the use of a new technology or techniques is critical in order to establish the appropriate indications for a new procedure and for future surgeon innovators to learn from these experiences.

An enhanced understanding of the biology of musculoskeletal disease and advances in computerized technology, materials science, and human genetics will promote technological developments that will improve outcomes for our patients. As revolutionary changes occur in orthopaedics, surgeons must ensure that the protection of patient safety remains the highest priority. New technology should be incorporated into our practices only when it can be shown to enhance outcomes and to be cost-effective, or we will lose the public's trust.

Conclusions

Minimally invasive total hip arthroplasty provides a potentially valuable new variation on a well-established and widely used technology. It is hard not to see the potential value—and potential risk—of quicker rehabilitation and shorter hospital stays. The possible future marriage of minimally invasive operative methods with image-guided surgery and computer navigation methods also is intuitively appealing. However, many questions remain about the short-term results of these operations and whether they can be performed with the same level of safety and efficacy as a conventional total hip arthroplasty. There are no long-term data comparing the durability of reconstructions performed through these approaches with conventional total hip arthroplasty. Practitioners must decide what level of evidence demonstrating safety and efficacy will be needed before they consider using so-called minimally invasive methods. Surgeons who are advocates will need to explore and refine indications and contraindications, define optimal patient populations, and understand the limitations of minimally invasive methods. If these methods prove to be valuable, the best methods to teach the techniques to surgeons in practice, and during training, will need to be considered.

Often overlooked in the discussion on minimally invasive total hip arthroplasty is the role that an integrated program of anesthesia and accelerated rehabilitation that is instituted with minimally invasive methods may play in facilitating shorter hospital stays. Also, an objective evaluation of the degree to which patient selection and changes in patient expectations may contribute to perceived improvements in pain relief and shortened hospital stays needs to be considered. Unless carefully designed and executed studies are performed in the future, it will be difficult to disentangle the effects of patient selection, altered patient expectations, and radically changed perioperative management from those of the changed surgical approach itself. It is of note that, for all of the series reported in this symposium, the surgeons not only made changes in the operative approach for total hip arthroplasty but also made changes in the anesthetic protocol, perioperative pain management protocols, and rehabilitation protocols. No one can foresee with certainty whether the current methods of minimally invasive total hip arthroplasty will be widely adapted, used on a selective basis, or used very little in the future. Almost without doubt, however, efforts to develop minimally invasive total hip arthroplasty will have an effect on how conventional total hip arthroplasty is performed. For instance, optimal placement and use of incisions can reduce the length of the incision in some patients, and better retractors, bone preparation instruments, and implant insertion instruments will allow surgeons to use conventional methods with less soft-tissue dissection. The success of accelerated rehabilitation protocols with minimally invasive methods may demonstrate that rehabilitation after most conventional total hip arthroplasties can be accelerated. Better anesthetic techniques pioneered for minimally invasive surgery may

also benefit many patients who are treated with conventional total hip arthroplasty.

New procedures often are greeted with great enthusiasm, particularly as early positive results are reported by the developers, who are also experts in applying the technology. Subsequently, as the technology is disseminated **more** widely, problems related to the procedure often are identified and a retrenchment in enthusiasm may follow. Technologies are adapted as an enduring part of practice only if a sufficient number of surgeons become experts in the technology, the operative indications and methods allow the procedure to be performed at least as safely and reliably as previously available procedures, and the long-term results match or exceed those of conventional, established methods. Greater experience and longer detailed follow-up with careful comparison with conventional hip arthroplasty will direct the future course of minimally invasive total hip arthroplasty. ■

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