

# *NIH Consensus Statement*

Volume 12, Number 5  
September 12-14, 1994



## *Total Hip Replacement*

NATIONAL INSTITUTES OF HEALTH  
Office of the Director

## **About The NIH Consensus Development Program**

NIH Consensus Development Conferences are convened to evaluate available scientific information and resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

Free copies of this statement and bibliographies prepared by the National Library of Medicine are available from the NIH Consensus Program Information Service at 1-800-NIH-OMAR (644-6627) or from the Office of Medical Applications of Research, National Institutes of Health, Federal Building, Room 618, 7550 Wisconsin Avenue MSC9120, Bethesda, MD 20892-9120.

## **Reference Information**

For making bibliographic reference to the consensus statement from this conference, it is recommended that the following format be used, with or without source abbreviations, but without authorship attribution:

Total Hip Replacement. NIH Consensus Statement 1994  
Sep12-14; 12(5): 1-31.



# ***NIH Consensus Statement***

---

Volume 12, Number 5  
September 12-14, 1994

## ***Total Hip Replacement***

*This statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.*

# Abstract

## Objective

To provide physicians with a current consensus on total hip replacement.

## Participants

A non-Federal, nonadvocate, 13-member consensus panel representing the fields of orthopedic surgery, rehabilitation and physical medicine, biomechanics and biomaterials, internal medicine, public health, geriatrics and biostatistics, and a public representative. In addition, 27 experts in orthopedic surgery, rehabilitation and physical medicine, biomechanics and biomaterials, rheumatology, geriatrics, and epidemiology presented data to the consensus panel and a conference audience of 425.

## Evidence

The literature was searched through Medline and an extensive bibliography of references was provided to the panel and the conference audience. Experts prepared abstracts with relevant citations from the literature. Scientific evidence was given precedence over clinical anecdotal experience.

## Consensus

The panel, answering predefined consensus questions, developed their conclusions based on the scientific evidence presented in open forum and the scientific literature.

## Consensus Statement

The panel composed a draft statement that was read in its entirety and circulated to the experts and the audience for comment. Thereafter, the panel resolved conflicting recommendations and released a revised statement at the end of the conference. The panel finalized the revisions within a few weeks after the conference.

## **Conclusions**

Total hip replacement is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment. Most patients have an excellent prognosis for long-term improvement in symptoms and physical function. At this time, a cemented femoral component using modern cementing techniques, paired with a porous-coated acetabular component, can give excellent long-term results. Revision of a total hip replacement is indicated when mechanical failure occurs. Continued periodic follow-up is necessary to identify early evidence of impending failure so as to permit remedial action before a catastrophic event.

## Introduction

More than 120,000 artificial hip joints are being implanted annually in the United States. Successful replacement of deteriorated, arthritic, and severely injured hips has contributed to enhanced mobility and comfortable, independent living for many people who would otherwise be substantially disabled. New technology involving prosthetic devices for replacement of the hip, along with advances in surgical techniques, has diminished the risks associated with the operation and improved the immediate and long-term outcome of hip replacement surgery.

Questions remain, however, concerning which prosthetic designs and materials are most effective for specific groups of patients and which surgical techniques and rehabilitation approaches yield the best long-term outcomes. Issues also exist regarding the best indications and approaches for revision surgery.

As a followup to the National Institutes of Health (NIH) Consensus Development Conference (CDC) on Total Hip Joint Replacement held in 1982, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, together with the Office of Medical Applications of Research of the NIH, convened a second CDC on Total Hip Replacement on September 12–14, 1994. The conference was cosponsored by the National Institute on Aging, the National Institute of Child Health and Human Development, and the Office of Research on Women's Health. After 1<sup>1/2</sup> days of presentations by experts in the relevant fields and discussion by a knowledgeable audience, an independent, non-Federal consensus panel composed of specialists from the fields of orthopedic surgery, epidemiology, rehabilitation and physical medicine, biomechanics and biomaterials, geriatrics, rheumatology, as well as a public representative, weighed the scientific evidence and formulated a consensus statement in response to the following six previously stated questions:

- What are the current indications for total hip replacement?

- What are the design and surgical considerations relating to a replacement prosthesis?
- What are the responses of the biological environment?
- What are the expected outcomes?
- What are the accepted approaches and outcomes for revision of a total hip replacement?
- What are the most productive directions for future research?

This consensus statement reflects a synthesis of generally accepted observations and recommendations derived from the scientific presentations as well as a general review of current literature by the consensus panel. This panel also identified areas of limited information where further research would be most productive.

## What Are the Current Indications for Total Hip Replacement?

Primary total hip replacement (THR) is most commonly used for hip joint failure caused by osteoarthritis; other indications include, but are not limited to, rheumatoid arthritis, avascular necrosis, traumatic arthritis, certain hip fractures, benign and malignant bone tumors, the arthritis associated with Paget's disease, ankylosing spondylitis, and juvenile rheumatoid arthritis. The aims of THR are relief of pain and improvement in function. Candidates for elective THR should have radiographic evidence of joint damage and moderate to severe persistent pain or disability, or both, that is not substantially relieved by an extended course of nonsurgical management. These measures usually include trials of analgesic and nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, the use of walking aids, and reduction in physical activities that provoke discomfort. In certain conditions such as rheumatoid arthritis and Paget's disease, additional disease-specific therapies may be appropriate. The patient's goals and expectations should be ascertained prior to THR to determine whether they are realistic and attainable by the recommended therapeutic approach. Any discrepancies between the patient's expectations and the likely outcome should be discussed in detail with the patient and family members before surgery.

In the past, patients between 60 and 75 years of age were considered to be among the best candidates for THR. Over the last decade, however, the age range has been broadened to include more elderly patients, many of whom have a higher level of comorbidities, as well as younger patients, whose implants may be exposed to greater mechanical stresses over an extended time course. In patients less than 55 years of age, alternative surgical procedures such as fusion and osteotomy deserve consideration. However, there are no data showing that the outcomes of these procedures are as good or better than those from THR when performed for similar indications. Advanced age alone is not a contraindication for THR; poor outcomes appear to be related to comorbidities rather than to age.

There are few contraindications to THR other than active local or systemic infection and other medical conditions that substantially increase the risk of serious perioperative complications or death. Obesity has been considered a relative contraindication because of a reported higher mechanical failure rate in heavier patients; however, the prospect of substantial long-term reduction in pain and disability for heavier patients appears to be similar to that for the population in general.

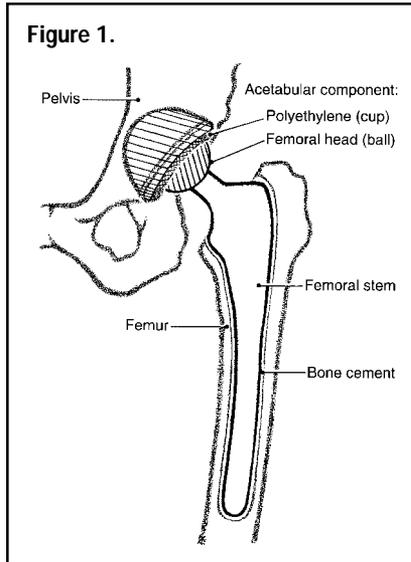
Thus, although the clinical conditions and circumstances leading to THR are broadly defined, several issues regarding indications remained unresolved. For example, data are insufficient on the associations between potential risk factors (e.g., age, weight, smoking, medications) and outcomes to guide treatment of the individual patient. Moreover, indications are not clear for use of the various surgical approaches and types of prostheses in individual patients. Finally, standardized instruments to measure levels of pain, physical disability, and quality of life as perceived by the patient need to be used to guide clinical decisionmaking and choice of surgery.

# What Are the Design and Surgical Considerations Relating to a Replacement Prosthesis?

At the NIH CDC on Total Hip Joint Replacement held in 1982, aseptic loosening was identified as a major problem with THR. It was especially prevalent in young, active patients and after revision surgery. Because it appeared with increasing frequency over time, it was feared that a much larger problem would emerge. Newer fixation (cement and cementless) techniques had been introduced, but their long-term efficacy was unknown. Cobalt-, titanium-, and iron-based alloys, higher molecular weight polyethylene, and autocuring polymethylmethacrylate (PMMA) bone cement were the materials used in most implants. Chemical modifications and altered processing of the alloys had been introduced to deal with the problem of fractured stems.

As of 1994, state of the art pertaining to THR has changed substantially. For example, changes have been made in fixation (cement and cementless), device designs, and some materials (see the THR schematic drawing shown in Figure 1). Concerns remain about

the *in vivo* durability of femoral and acetabular components of the implants, but the procedure has a more predictable outcome. The newer cementing techniques have proven to be more successful than the original ones on the femoral side. Improved techniques include the use of a medullary plug, a cement gun, lavage of the canal, pressurization, centralization of



the stem, and reduction in porosity in the cement. However, the optimum cement–metal interface has yet to be identified. These newer procedures minimize defects and localized stress concentrations in the cement. Their current success indicates that previously observed aseptic loosening within the first 10 years following implantation was primarily a mechanical process and that steps to reduce stresses in the materials and improve strength of the interfaces are reasonable to reduce loosening. Further optimization of the bone implant interface constitutes an important opportunity for future research.

Another important change in fixation has been the introduction and widespread use of noncemented components that rely on bone growth into porous or onto roughened surfaces for fixation. In the femur, selected cementless components have exhibited clinical success, although with shorter followup, similar to that of cemented components installed with the newer cementing techniques. There is evidence that bone changes (osteolysis or bone resorption) can occur as well with some of the cementless components. Numerous reports document resorption, and although it has not usually become symptomatic during early stages of followup, concerns nevertheless exist about progressive osteolysis and consequent aseptic loosening or fracture.

On the acetabular side, the cementless components have demonstrated less aseptic loosening compared with the cemented components over the short term, although long-term results are not yet available. The prospective and retrospective studies conducted have been specific to device design and technique, and any general comparison of cemented and noncemented systems should be viewed with caution.

The implants themselves have undergone multiple changes. As a result of improved alloys and designs, fracture of femoral stems is no longer a significant problem. Stem cross-sections have been rounded to avoid high stresses in the cement. There is still controversy over the appropriate length of uncemented stems and the extent and location of porous

or roughened regions. Metal backing of cemented acetabular components has not been associated with a high degree of success and is now used infrequently. Metal-backed acetabular components with porous coatings have demonstrated good to excellent results in regard to loosening noted at 5- to 7-year followup and continue to be followed. Modular components have been introduced and are widely used, but it is recognized that *in vivo* disassembly, fretting and corrosion, and wear between components can be a source of debris and may contribute to osteolysis and isolated implant fractures. Given the potential problems, routine use of modular components needs to be evaluated specific to particular applications. There appears to be little justification for modularity or customization of femoral stems below the head-neck junction in primary THR, although the modular stem components for revisions may be useful.

Revision rates for cemented femoral components, using modern techniques, have been reported to be less than 5 percent at 10-year followup; revision rates for uncemented acetabular components are approximately 2 percent at 5-year followup. To be deemed efficacious, new design features should be shown to have a mechanical failure rate equal to or lower than these figures.

As in 1982, the primary implant materials are cobalt- and titanium-based alloys, PMMA bone cement, and ultrahigh molecular weight polyethylene. These continue to demonstrate biocompatibility in bulk, but particles of these materials, particularly the polyethylene, are suspected to have a role in bone resorption and potential implant loosening. Osteolysis that can occur with both cemented and cementless components on both the femoral and acetabular sides is thought to be due to an inflammatory process brought on by particulate matter. The articulating surfaces between the femoral and acetabular components are now recognized as a major source of debris, which has been shown to be important in this pathologic tissue response. Most components for femoral heads have polished cobalt alloy, which articulates with polyethylene sockets. Longitudinal research continues

on smoothness and ion implantation of the articulating surfaces, ceramic–polymer, ceramic–ceramic, and alloy–alloy components, although the *in vivo* data remain limited at this time. Efforts to alter or replace the polyethylene are under way, but no new materials with reduced clinical wear rates are routinely available.

Several factors have been suggested to minimize the production of wear debris. Polyethylene acetabular cups with minimum wall thickness of 6 mm and femoral heads with diameters of 28 mm are important design considerations associated with reduced wear. Where metallic shells are used to contain the polyethylene cup, the interior of the shell should be smooth with a minimum number of openings for screws, and the polyethylene liner should be highly conforming and mechanically stable. Polyethylene of the highest quality is strongly advised for the manufacture of the components. Femoral heads with highly polished cobalt alloy, or polished ceramics as some data suggest, may be advantageous to minimize effects of wear on the polyethylene surface.

Studies also continue on surface modifications of implants to provide direct attachment to bone. For example, several types of calcium phosphate ceramics (CPC) (often called hydroxylapatite) have been added as coatings to THR surfaces to enhance fixation of noningrowth implants to bone. Concerns have been expressed about the longer term *in vivo* fatigue strengths of the substrate to coating interfaces, biodegradation, and the potential for generating ceramic particulates, although so far data addressing implant performance are comparable to those from other device designs at the same followup times. Research and development on the enhancement of bone growth into porous biomaterials using CPC has also shown promise, although longitudinal data are incomplete at this time. Long-term data are needed on the benefit-to-risk ratio of clinical outcomes for these types of surface modifications.

Although there are *in vitro* tests for evaluating implant design features and material characteristics, as well as animal testing regimens, the relevance of these tests to *in vivo* human

performance are often unknown and additional approaches are necessary. Long-term clinical studies are the only accepted method for evaluating the efficacy of the design and materials in human use, particularly with regard to patient-defined outcome measures. Since these take many years and are very expensive, few implant design features are supported by well-designed studies.

Adaptive bone remodeling around the prosthesis continues to be a concern, but there is little evidence that it is a significant clinical problem during the first 10 years of followup. Joint forces are known with better confidence than in 1982, but it is still unknown which elements of force, magnitude, and time are relevant to implant failures. Detailed analysis of stress distribution is still limited by imprecise data on joint forces, viscoelastic properties, and failure modes of the materials and tissues.

In 1994, the main problems of concern related to implant design are long-term fixation of the acetabular component, osteolysis due to particulate materials, biologic response to particles of implant materials, and the less favorable results of revision surgery.

## What Are the Responses of the Biological Environment?

Since the NIH CDC on Total Hip Joint Replacement held in 1982, bone resorption, or osteolysis, has emerged as the major concern with regard to the long-term survival of total hip arthroplasty. Significant resorption and massive osteolysis as well as more limited areas of bone destruction had been associated with cemented components and attributed to cement debris. Subsequent findings confirm that similar problems can be associated with cementless prosthetic implants, and some degree of osteolysis may be present in up to 30–40 percent of cases within 10 years of surgery. Both acetabular and femoral components may be affected. Components may remain well fixed in the presence of significant bone loss, but indications are that once osteolysis appears it tends to progress and may ultimately lead to implant failure. This bone loss is now considered to be a reaction to particulate matter derived from the implanted prosthetic components as well as the cement when used. Because osteolysis is an important contributor to failure of hip arthroplasties and may occur in the absence of clinical symptoms, it is important that patients with implants be followed and evaluated at regular intervals throughout life to ensure timely operative intervention, if necessary.

Quantitatively, the material causing the most tissue reaction appears to be particulate polyethylene. These particles have been recovered in significant quantities from periprosthetic tissues, including sites remote from the source. Particle size varies, but the majority recovered are approximately 0.5  $\mu\text{m}$ , with 90 percent less than 1.0  $\mu\text{m}$ . It has been estimated that the average rate of wear for cobalt alloy-to-polyethylene interface is 0.1–0.2 mm/year. The volume of wear debris may increase with larger femoral head size.

Metallic debris has also been identified in significant quantities. The source may be related to stem–bone fretting, particularly in loose prostheses and in more distal portions of proximally fixed prostheses where significant motion between stem and bone may persist. With the use of modular prostheses, corrosion and/or fretting have been identified in up to 35

percent of some retrieved specimens, and these connections could serve as a source of metallic particles. Fretting and corrosion are not limited to the interface between dissimilar alloys. Interactions have also been identified with cobalt–cobalt and titanium–titanium as well as titanium–cobalt alloy junctions. Reactions at the head–neck junctions have been studied in depth. Corrosion and wear debris products can also form at the interfaces between screws and acetabular shells and at modular collars for adapting proximal femoral stems. Some of the metallic particles generated may be larger than the polyethylene debris. The major effect of these larger metallic debris may relate to promoting third body wear of the polyethylene, with the derivative polyethylene particles of submicron size triggering the cellular response. However, smaller metal particles and ions have been demonstrated to be active in direct stimulation of biologic processes.

The leading hypothesis to explain the development of massive osteolysis is that particulate matter derived from prosthetic components and cement stimulates an inflammatory response. Phagocytosis of the particles by macrophage and foreign-body giant cells (arising from the macrophage) appears to be the initial biologic response to particulate matter. The presence of intracellular particles is associated with the release of cytokines and other mediators of inflammation. These factors initiate a focal bone resorptive process largely mediated by osteoclasts. These osteoclasts do not contain debris particles.

Thus, the long-term threat to component failure from a biologic standpoint appears to be wear-debris-associated periprosthetic osteolysis as a result of osteoclastic activity. This is stimulated by cytokines such as tumor necrosis factor, interleukins, and prostaglandins released by macrophages and possibly other cells including fibroblasts. The critical initiating sequence involves the interaction between small particulate materials and responding cells. The process is affected by the number, size, distribution, and type of particulate material, as well as responsiveness of the ingesting cells.

The debris may be distributed beyond the hip joint. Material has been identified in distant lymph nodes, but no systemic consequences are documented up to this time. Since it is now recognized that both cobalt- and titanium-based alloys release soluble products in patients, long-term surveillance to assess possible systemic and remote side effects after THR is advisable.

Adaptive bone remodeling occurs in the proximal femur in response to an altered mechanical environment following hip replacement. This process is commonly referred to as “stress shielding” or stress transfer. Stem rigidity or elasticity plays a major role. Bone resorption in unstressed areas is a common observation, but it has not been shown to be related to loosening. Nevertheless, it presents an important concern in terms of long-term stability and effect on revision surgery.

Factors influencing adaptive bone remodeling have been considered in determining the location and extent of porous coating on uncemented stems. Finite element analysis suggests that proximally coated porous stems are associated with less cortical bone stress shielding than fully coated stems, but the extent of coating on most currently used prosthetic stems is still greater than that calculated necessary to significantly reduce the stress-shielding effect on the proximal femur. Decreasing porous coating to reduce stress shielding must be weighed against providing sufficient coating to ensure fixation. Efforts to reduce stem stiffness have been shown to lessen proximal cortical atrophy under experimental conditions.

## What Are the Expected Outcomes?

The success of THR in most patients is strongly supported by nearly 30 years of followup data. There appears to be immediate and substantial improvement in the patient's pain, functional status, and overall health-related quality of life. Promising data suggest that these immediate improvements persist in the long term. Over the last two decades, complications associated with THR have declined significantly. Prophylactic antibiotic therapy has helped to prevent infection. Use of anticoagulants in the perioperative period has reduced deep venous thrombosis and pulmonary emboli. The incidence of mechanical loosening has decreased with the introduction of improved fixation techniques. More than 90 percent of all artificial joints are never revised. Rates of revision are decreasing with improved surgical techniques.

The important questions of today are not whether THR is effective compared with no treatment but rather which technology and methodology used for THR are best for a particular patient. For example, the various total hip designs, fixation methods, and surgical techniques need to be rigorously compared with one another. Surgeon's experience and hospital environment should be investigated for possible independent effects. Various rehabilitation interventions, including long-term therapeutic exercise, should be evaluated for effectiveness. Similarly, little is known about patient-level predictors of outcome, e.g., patient expectations, quality of the individual patient's bone stock, demographic characteristics, comorbidities, obesity, and activity level.

Since length of acute hospital stay has become progressively shorter, more emphasis must be given to determining the role of preadmission educational programs, appropriate physical therapy, and rehabilitation during the acute stay and following discharge. Home health programs when indicated may be more effective than prolonged hospitalization. The benefits of a long-term therapeutic exercise program for patients who have undergone THR have not been clearly demonstrated to improve mobility or hip stability. There

appears to be insufficient appreciation for the role of exercise in THR rehabilitation; however, there is evidence that hip weakness persists up to 2 years after surgery in the presence of a normal gait. Multiple studies have demonstrated that weakness in the lower extremities is a major risk factor for falls in the geriatric age group. Thus, further studies are needed to assess the relationship between muscle function following THR, mobility, and risk for falls, as well as the role of therapeutic exercise in improving muscle function with enhancement of mobility and stability.

Outcome assessment in THR has been limited by the lack of standardized terminology and by the use of various scales that have traditionally relied on the surgeon's assessment of the patient's pain, range of motion, muscle strength, and mobility. Most of these measures have not been adequately characterized in terms of validity, reliability, and responsiveness to change. The traditional assessments have not included patient-oriented evaluation of function or satisfaction. There is no consensus on the standard definitions of endpoints with respect to prosthesis failure. The American Academy of Orthopaedic Surgeons has developed recommendations for data to be collected, and this approach should be endorsed for use in clinical practice. The patient's functional status should be further assessed in followup by standardized, patient-reported, disease-specific measures and by at least one global outcome measure. Finally, the radiographic and clinical criteria for prosthesis failure should be defined.

Long-term followup is essential to determining outcomes and pathological processes (e.g., failures related to osteolysis and particulate debris). These complications were not emphasized in the 1982 CDC on Total Hip Joint Replacement. The problems have been identified only by long-term followup of patients.

Methodological issues that have limited THR outcomes assessment include lack of randomized trials and other well-controlled studies, lack of well-characterized patient cohorts for prospective observational studies, and insufficient sample sizes followed for prolonged periods of time.

THR is performed more than 120,000 times per year in the United States. This represents a 64-percent increase in the number of THR procedures per year in the United States since the 1982 CDC. Analysis of Medicare claims data demonstrates significant variations in the rates of performance of THR with respect to geography, age, gender, and race. The highest rates of THR are in the Midwest and Northwest and the lowest rates in the South and East. A fourfold difference exists between the State with the highest rate of THR (Utah) and the State with the lowest rate (Wyoming). A previous study demonstrated a 50-percent higher rate of THR in Boston, Massachusetts, compared with New Haven, Connecticut. Other procedures such as hip fracture repair have very low variation from one geographical area to another. In today's era of cost-containment and outcomes research, it is important to understand the factors contributing to these wide area variations as well as which rate of THR is most appropriate.

Sixty-two percent of all THR procedures in the United States are performed in women. Furthermore, women have significantly worse preoperative functional status than do men and are 35 percent more likely to report the use of a walking aid at the time of surgery. These differences persist even after adjustment for other demographic and clinical characteristics. These data suggest that, compared with men, women are being operated on at a more advanced stage of the disease. Two-thirds of all THR procedures are performed in individuals who are older than 65 years of age. The rate of THR increases for patients up to 75 years of age and then declines. The highest age-specific incidence rates of THR are between 65 and 74 years of age for men and 75 and 84 years of age for women. Recent comparisons of rates of THR reveal that more are being done in the young and in the oldest patients. Among the older patients, there has been an increase in THR in patients with more comorbidities.

Most THR procedures are performed in whites. The prevalence rate of hip implants (fixation devices and artificial joints) was 4.2 per 1,000 in whites compared with 1.7 per 1,000 in African-Americans. The disparity by race increases markedly with age. These findings were confirmed by an analysis of

Medicare claims data that focused solely on THR. Observed differences in the rate of THR by race may reflect a disparity in access or referral for care for African-Americans. Additionally, individuals with higher income were 22 percent more likely to undergo THR than were individuals with low income. Health care providers and patients must be cognizant of the variations in the THR rate. It is important to carefully consider the potential influence of access to care, treatment selection biases, and patient knowledge and preferences on these variations in rates.

In this era of cost-containment and managed care, the ultimate selection of a THR system should be based on individualized patient needs, safety, and efficacy. There is consensus that the THR patient requires periodic followup including appropriate x-ray examination throughout life. Periodic followup, perhaps at 5-year intervals after the first 5 years, could allow identification of osteolysis and other indicators of impending failure in their earliest forms and permits institution of treatment before catastrophic failure.

## What Are the Accepted Approaches and Outcomes for Revision of a Total Hip Replacement?

As more primary THRs occur on a cumulative basis, as indications extend to more conditions and to older and younger individuals, and as the population ages, the absolute number of revision hip replacements will increase, even if the frequency of failures in primary procedures continues to decrease. Revision surgery is highly complex and costly and requires considerable scientific and technical expertise, an array of expensive technological options, a supportive health care environment, and a skilled health care team. Consequently, issues such as the surgeon's experience, the hospital characteristics, the related health care costs, and appropriateness of current hospital reimbursements associated with revision should be carefully examined.

Currently, the results of revision THR are inferior to those of primary procedures. It remains important to refine the indications for revision and to do so on the basis of the best available outcome data. Not all "failed" primary THRs require revision. The decision to revise, as is true of decisions regarding primary procedures, must consider such circumstances as the presence of disabling pain, stiffness, and functional impairment unrelieved by appropriate medical management and lifestyle changes. In addition, radiographic evidence of bone loss or loosening of one or both components should be present. Indeed, evidence of progressive bone loss alone provides sufficient reason to consider revision in advance of catastrophic failure. Fracture, dislocation, malposition of components, and infection involving the implant are other reasons to consider revision.

A number of options must be considered in planning a revision operation. The selection of specific technology is currently a judgment of the surgeon and depends on the amount and quality of the bone stock, the age and functional demands of the patient, and the reason for failure of the primary procedure.

The weight of clinical experience suggests that a loose acetabular component, either cemented or porous coated, can be reliably replaced by a porous-coated component in the presence of adequate bone stock. In one study using this approach, 91 percent of implants were radiographically stable and 9 percent required re-revision (for dislocation and infection rather than aseptic loosening) between 8 and 11 years after revision. In elderly patients with lower functional demands and those with osteogenic bone, cemented implants have also provided satisfactory results. To achieve prosthetic stability in the absence of sufficient bone stock, deficits can be filled with morselized or structural bone grafts (either autografts or allografts obtained from accredited tissue banks), customized metal components, or, under some circumstances, bone cement.

The approach to revision of the femoral component must be based on the nature of the remaining bone stock in the proximal femur, and clinical judgment usually takes into account the age and functional demands of the patient. Under many circumstances, revision of the femoral component with a cemented stem is possible using modern cementing techniques. The re-revision rate for this approach is between 10 and 18 percent at 10- to 11-year followup.

An acceptable alternative approach to revision of femoral components when there is substantial residual bone stock has been the use of noncemented implants, particularly the extensively coated components. This approach has resulted in 90-percent stem survivorship at a 9-year followup.

Morselized bone graft can be used successfully to fill defects in the femoral canal with or without the use of bone cement, and cortical bone can be augmented with only grafts as necessary. Under exceptional circumstances, it may be necessary to use large structural allografts when the proximal femoral bone stock deficiency is substantial. If this is done, the implant should be cemented into the graft.

Both the diagnosis and the treatment of infected implants remain challenging. The infection rates of the past have been dramatically reduced. Current infection rates of less than 1 percent at 1 year after primary THR are now being reported.

Nonetheless, infection remains a devastating complication, and treatment alternatives remain controversial. Recovery of the infecting organism is essential to the selection of appropriate antibiotics and the planning of surgical approaches. For organisms highly susceptible to multiple antibiotics, one-stage surgical approaches that combine extensive debridement and an ensuing exchange of implants are associated with a 77- to 94-percent success rate. Two-stage revisions that include at least 4 weeks of appropriate antibiotic treatment following implant removal and wound debridement and a variable period of time before reinsertion determined by the characteristics of the organism have resulted in a success rate greater than 80 percent. In young people, there may be value to a third, intermediate stage in which the bone stock is augmented in anticipation of later reimplantation.

## What Are the Most Productive Directions for Future Research?

THR is acknowledged as a highly successful procedure that has provided relief of pain, increased mobility, and improved tolerance for activity for thousands of people. Despite the advances made in the past decade, obvious deficiencies in knowledge remain regarding treatment alternatives, patient characteristics, and environmental issues. To address these concerns most effectively, it is important to identify those avenues of investigation that will lead to decreased morbidity and enhanced quality of life for the population at large affected by debilitating hip disease.

Standardized instruments for assessing outcomes need to be developed, validated, and introduced into clinical use. These may also be useful in developing guidelines for surgery and in making physicians aware of their patients' physical capabilities and expectations.

The issues of age, sex, weight, activity level, and comorbidities have been implicated for their effects on the outcome of THR and need to be studied in relation to the indications for surgery and timing of the procedure.

Serious questions have been raised concerning the disparate rates for THR between racial groups and geographic locations that seem to have no direct relationship to incidence of disease. In-depth analysis of rate differential can lead to an identification of underlying reasons. In this way, the benefits of THR can be extended to an appropriate segment of the population that appears to have limited access.

Materials currently used for the manufacture of THR implants have been improved with regard to design and finish. Wear debris, however, remains a factor that affects the durability of the implants and their fixation. Research is ongoing and support is needed to expand investigations of new materials and to create a better understanding of wear processes that can prolong the life of the implant and reduce the wear and wear products.

One of the necessary approaches for evaluating implant failure modes is an organized, ongoing analysis of *in situ* prostheses retrieved from cadavers. Such a program should be national in scope and supported by grant monies. As part of this effort, it is anticipated that significant data could be obtained concerning wear processes involving the articular surfaces under circumstances where the implant did not fail. At the same time, this avenue of research would further clarify the device and tissue interactions that are characteristic of the cemented and noncemented types of devices.

Randomized clinical trials are needed to determine the efficacy of implant designs and surgical approaches, including the effect of coatings that encourage appositional or interpositional bone growth for fixation.

The contribution of prehospital, inhospital, and posthospital education and rehabilitation programs to the eventual outcome of the surgical procedure deserves an organized, indepth study to determine optimum regimen, duration of treatment, and expected outcomes. Clinical data suggest that potential capabilities of the patients are not being fully developed.

The biologic interface between the implant and the host bone has been recognized as a source of potential failure. Basic research efforts into the mechanisms by which these changes occur are providing some clues, but much more needs to be known about specific cellular mechanisms associated with osteolysis, suggested immunologic or inflammatory responses, and the reactions to varying stresses encountered by the bone. In addition, further investigation should be encouraged into the ways by which the local inflammatory response to particulate matter could be modified by regional or systemic interventions.

As the indications for THR are extended into the younger age group, patients with THR will be exposed to more rigorous environmental demands, both occupational and recreational. Investigations are needed into the environmental modifications, activity limitations, or types of

physical effort that contribute to extended prosthesis survival. Physical conditioning activities—muscle development, improvement in coordination, and exercises that enhance bone integrity without affecting fixation—need to be studied as they relate to the anticipated lifestyle and occupational objectives of the patient.

Outcomes of revision hip surgery are less reliable and satisfactory than those of primary procedures. Those biologic, biomechanical, and rehabilitation factors that influence these results need to be explored and solutions developed.

Regional or national registries should be established to capture a minimum data set on all THR and revision procedures. The goals of this registry should be to better define the natural history and epidemiology of THR in the U.S. population as a whole and to identify risk factors for poor outcomes that relate to the implant, procedure, and patient characteristics.

## Conclusions

- THR is an option for nearly all patients with diseases of the hip that cause chronic discomfort and significant functional impairment.
- In the aggregate, THR is a highly successful treatment for pain and disability. Most patients have an excellent prognosis for long-term improvement in symptoms and physical function.
- Perioperative complications such as infection and deep venous thrombosis have been significantly reduced because of use of prophylactic antibiotics and anticoagulants and early mobilization.
- The predominant mode of long-term prosthetic failure appears to be related to generation of particulate matter, which in turn causes an inflammatory reaction and subsequent bone resorption around the prosthesis.
- Revision of THR is indicated when mechanical failure occurs. The surgery is technically more difficult and the long-term prognosis is generally not as good as for primary THR. The optimal surgical techniques for THR revision vary considerably depending on the conditions encountered. Continued periodic followup is necessary to identify early evidence of impending failure so as to permit remedial actions before a catastrophic event.
- Improved methods for evaluating existing technology should be developed and implemented, especially with respect to patient-defined outcomes.
- Future research should focus on refining indications for surgery; defining reasons for differences in procedure rates by age, race, gender, and geographic region; developing surgical techniques, materials, and designs that will be clearly superior to current practices; understanding the inflammatory response to particulate material and how to modify it; determining optimal short- and long-term rehabilitation strategies; and elucidating risk factors that may lead to accelerated prosthetic failure.

## Consensus Development Panel

### **David G. Murray, M.D.**

*Panel and Conference  
Chairperson*

*Professor and Chairman*  
Department of Orthopedic  
Surgery  
State University of New York  
Health Sciences Center  
Syracuse, New York

### **Renée S. Crown**

Wilmette, Illinois

### **Kay Dickersin, Ph.D.**

*Assistant Professor*  
Department of Epidemiology  
and Preventive Medicine  
School of Medicine  
University of Maryland  
at Baltimore  
Baltimore, Maryland

### **Pamela Woods Duncan, Ph.D., P.T.**

*Director of Research*  
Center for Aging  
Kansas University Medical Center  
Kansas City, Kansas

### **Charles H. Epps, Jr., M.D.**

*Vice President, Health Affairs*  
Howard University  
Washington, District of Columbia

### **Walter H. Ettinger, Jr., M.D.**

*Professor of Internal Medicine  
and Public Health Sciences*  
Department of Internal Medicine  
Bowman Gray School  
of Medicine  
Winston-Salem, North Carolina

### **Gary E. Friedlaender, M.D.**

*Professor and Chairman*  
Department of Orthopaedics  
and Rehabilitation  
Yale University School  
of Medicine  
New Haven, Connecticut

### **Joseph M. Lane, M.D.**

*Professor and Chairman*  
Department of Orthopaedic  
Surgery  
UCLA School of Medicine  
Los Angeles, California

### **Jack E. Lemons, Ph.D.**

*Professor, Departments of  
Biomaterials and Surgery*  
Division of Orthopaedic Surgery  
University of Alabama  
at Birmingham  
Birmingham, Alabama

### **Jack L. Lewis, Ph.D.**

*Professor, Department of  
Orthopaedic Surgery*  
University of Minnesota  
Minneapolis, Minnesota

### **Ellen J. MacKenzie, Ph.D.**

*Professor, Health Policy  
and Management*  
School of Hygiene and  
Public Health  
Johns Hopkins University  
Baltimore, Maryland

### **Robert S. Pinals, M.D.**

*Professor, Department of  
Medicine/Rheumatology*  
The Robert Wood Johnson  
Medical School  
University of Medicine and  
Dentistry of New Jersey  
Department of Medicine  
Medical Center at Princeton  
Princeton, New Jersey

### **Paul S. Treuhhaft, M.D.**

*Orthopaedic Surgeon*  
Kolczun and Kolczun  
Orthopaedic Associates  
Lorain, Ohio

## Speakers

### **J. Dennis Bobyn, Ph.D.**

“Total Hip Replacement:  
Femoral Fixation”

*Director of Orthopaedic  
Research*

Montreal General Hospital  
McGill University  
Montreal, Quebec  
Canada

### **John J. Callaghan, M.D.**

“Prophylaxis for Deep Venous  
Thrombosis and Infection  
and Acetabular Preparation”

*Professor, Department of  
Orthopaedic Surgery*

University of Iowa Hospitals  
and Clinics  
Iowa City, Iowa

### **William N. Capello, M.D.**

“Outcomes With Special  
Devices”

*Professor, Department of  
Orthopaedic Surgery*

Indiana University School  
of Medicine  
Indianapolis, Indiana

### **Jane A. Cauley, Dr.P.H.**

“Epidemiology of Total Hip  
Replacement”

*Associate Professor  
Department of Epidemiology  
Graduate School of  
Public Health*

University of Pittsburgh  
Pittsburgh, Pennsylvania

### **Dwight T. Davy, Ph.D.**

“Joint Loads in Total Hip  
Arthroplasty”

*Professor, Department of  
Mechanical and Aero-  
space Engineering and  
Orthopaedics*

Case Western Reserve University  
Cleveland, Ohio

### **J. Robin deAndrade, M.D., F.R.C.S. (Eng. & C.), F.A.C.S., F.A.C.R.**

“Selected Issues in Postsurgical  
Management and Rehabilita-  
tion Following Total Hip  
Replacement”

*Professor, Department  
of Orthopedics*

Emory University School  
of Medicine  
Atlanta, Georgia

### **Charles A. Engh, M.D.**

“Cementless Total Hip  
Arthroplasty Outcomes:  
Extensively Porous-  
Coated Implants”

*Medical Director  
Anderson Orthopaedic  
Research Institute  
Anderson Clinic  
Arlington, Virginia*

### **Robert H. Fitzgerald, Jr., M.D.**

“Management of the Patient  
With an Infected Total  
Hip Replacement”

*Professor and Chairman  
Department of Orthopaedic  
Surgery*

Wayne State University  
School of Medicine  
Detroit, Michigan

### **Jorge O. Galante, M.D.**

“Acetabular Revision”  
*Professor of Orthopedic Surgery*

The Grainger Director  
Rush Arthritis Orthopedics  
Institute  
Rush-Presbyterian-St. Luke’s  
Medical Center  
Chicago, Illinois

### **Jeremy L. Gilbert, Ph.D.**

“Degradation in Modular  
Femoral Hip Prosthesis  
Tapers”

*Associate Professor  
of Biomaterials  
Northwestern University  
Chicago, Illinois*

**Victor M. Goldberg, M.D.**

“Technical Aspects of Inserting Cementless Femoral Components”  
*Professor and Chairman*  
Department of Orthopedics  
Case Western Reserve University  
Cleveland, Ohio

**Steven R. Goldring, M.D.**

“Local and Systemic Response to Wear Particles: Immune and Cellular Responses of Bone and Connective Tissues”  
*Chief, Rheumatology*  
Department of Medicine  
New England Deaconess Hospital  
Harvard Medical School  
Boston, Massachusetts

**William H. Harris, M.D.**

“Femoral Cementing Techniques”  
*Chief, Hip and Implant Unit*  
Massachusetts General Hospital  
Boston, Massachusetts

**Peter Herberts, M.D., Ph.D.**

“Indications for Revision of a Total Hip Replacement: Factors of Importance for Failures and Overview of Outcomes”  
*Professor, Department of Orthopaedics*  
Sahlgrenska University Hospital  
University of Göteborg  
Sweden

**David S. Hungerford, M.D.**

“Clinical Experience and Current Status of Proximally Coated Cementless Femoral Stems”  
*Chief of Orthopedic Surgery*  
Johns Hopkins University  
School of Medicine  
Good Samaritan Hospital  
Baltimore, Maryland

**Joshua J. Jacobs, M.D.**

“Particulate Wear”  
*Associate Professor*  
Department of Orthopedic Surgery  
Rush-Presbyterian-St. Luke’s Medical Center  
Chicago, Illinois

**Murali Jasty, M.D.**

“Acetabular Fixation”  
*Associate Clinical Professor of Orthopaedic Surgery*  
Massachusetts General Hospital  
Boston, Massachusetts

**Norman A. Johanson, M.D.**

“Principles of Outcomes Measures”  
*Associate Professor*  
Department of Orthopaedic Surgery  
Temple University School of Medicine  
Philadelphia, Pennsylvania

**David G. Lewallen, M.D.**

“Femoral Revisions: Cementless”  
*Associate Professor*  
Department of Orthopedic Surgery  
Mayo Clinic/Mayo Foundation  
Rochester, Minnesota

**William J. Maloney, M.D.**

“Cemented Outcomes: Modern Techniques”  
*Clinical Associate Professor*  
Stanford University  
Medical School  
*Attending Surgeon*  
Department of Orthopaedics  
Palo Alto Medical Clinic  
Palo Alto, California

**Cecil H. Rorabeck, M.D.,  
F.R.C.S.(C.)**

“Cost–Benefit Assessment  
of Total Hip Replacement”  
*Professor and Chairman*  
Division of Orthopaedic Surgery  
University Hospital  
London, Ontario  
Canada

**Harry E. Rubash, M.D.**

“Revision of the Femoral  
Component Using Cement”  
*Associate Professor and  
Clinical Vice Chairman*  
Department of Orthopaedic  
Surgery  
*Chief, Division of Adult  
Reconstructive Surgery*  
University of Pittsburgh  
Medical Center  
Pittsburgh, Pennsylvania

**Eduardo A. Salvati, M.D.**

“Outcomes of Cemented  
Total Hip Replacement  
of the First Generation”  
*Clinical Professor of  
Orthopedic Surgery*  
Hospital for Special Surgery  
New York, New York

**Clement B. Sledge, M.D.**

“Total Hip Replacement:  
Twelve Years Later—  
What Has Changed?”  
*Chairman, Department of  
Orthopedic Surgery*  
Brigham and Women’s Hospital  
Boston, Massachusetts

**Dale R. Sumner, Ph.D.**

“Local Bone Remodeling:  
Animal, Human, and  
Mathematical and  
Analytic Results”  
*Associate Professor*  
Department of Orthopedic  
Surgery  
Rush-Presbyterian-St. Luke’s  
Medical Center  
Chicago, Illinois

**Hans G. Willert, M.D.**

“Overview of Long-Term  
Interface Response”  
*Professor and Head of  
Orthopaedic Surgery*  
University of Göttingen  
Germany

**Timothy M. Wright, Ph.D.**

“Polyethylene”  
*Director, Department  
of Biomechanics*  
Hospital for Special Surgery  
New York, New York

## Planning Committee

### **Stephen Gordon, Ph.D.**

*Chairperson*

*Chief, Musculoskeletal  
Diseases Branch*

National Institute of Arthritis  
and Musculoskeletal and  
Skin Diseases  
National Institutes of Health  
Bethesda, Maryland

### **Daniel J. Chwirut, M.S.**

*Mechanical Engineer*

Division of Mechanics  
and Materials Science  
Food and Drug Administration  
Rockville, Maryland

### **Chhanda Dutta, Ph.D.**

*Director of Musculoskeletal  
Research*

Geriatrics Program  
National Institute on Aging  
National Institutes of Health  
Bethesda, Maryland

### **Jerry M. Elliott**

*Program Analyst*

Office of Medical Applications  
of Research  
National Institutes of Health  
Bethesda, Maryland

### **John H. Ferguson, M.D.**

*Director*

Office of Medical Applications  
of Research  
National Institutes of Health  
Bethesda, Maryland

### **Jorge O. Galante, M.D.**

*Professor of Orthopedic Surgery*

*The Grainger Director*  
Rush Arthritis and Orthopedics  
Institute  
Rush-Presbyterian-St. Luke's  
Medical Center  
Chicago, Illinois

### **William H. Hall**

*Director of Communications*  
Office of Medical Applications  
of Research

National Institutes of Health  
Bethesda, Maryland

### **Richard C. Johnston, M.D.**

*Clinical Professor of Orthopedics*

University of Iowa  
Des Moines Orthopedic  
Surgeons, P.C.  
Des Moines, Iowa

### **Daniel S. McGunagle**

*Chief, Orthopedic Devices  
Branch*

Food and Drug Administration  
Rockville, Maryland

### **David G. Murray, M.D.**

*Panel and Conference*

*Chairperson*  
*Professor and Chairman*  
Department of Orthopedic  
Surgery  
State University of New York  
Health Sciences Center  
Syracuse, New York

### **Louis A. Quatrano, Ph.D.**

*Chief, Applied Rehabilitation  
Medicine Research Branch*

National Center for Medical  
Rehabilitation Research  
National Institute of Child Health  
and Human Development  
National Institutes of Health  
Bethesda, Maryland

### **Judith S. Wortman**

*Technical Information Specialist*

Office of Scientific and Health  
Communications  
National Institute of Arthritis  
and Musculoskeletal and  
Skin Diseases  
National Institutes of Health  
Bethesda, Maryland

**Timothy M. Wright, Ph.D.**

*Director, Department of  
Biomechanics*

The Hospital for Special Surgery  
New York, New York

## Conference Sponsors

**National Institute of Arthritis  
and Musculoskeletal and  
Skin Diseases**

Lawrence E. Shulman, M.D.,  
Ph.D.

*Director*

**Office of Medical Applications  
of Research**

John H. Ferguson, M.D.

*Director*

## Conference Cosponsors

**National Institute on Aging**

Richard J. Hodes, M.D.

*Director*

**National Institute of Child Health  
and Human Development**

Duane F. Alexander, M.D.

*Director*

**Office of Research on Women's  
Health**

Vivian W. Pinn, M.D.

*Director*

## Statement Availability

Preparation and distribution of this statement is the responsibility of the Office of Medical Applications of Research of the National Institutes of Health. Free copies of this statement as well as all other available NIH Consensus Statements and NIH Technology Assessment Statements may be obtained from the following resources:

### **NIH Consensus Program Information Service**

P.O. Box 2577

Kensington, MD 20891

*Telephone* 1-800-NIH-OMAR (644-6627)

*Fax* (301) 816-2494

### **NIH Office of Medical Applications of Research**

Federal Building, Room 618

7550 Wisconsin Avenue MSC 9120

Bethesda, MD 20892-9120

Full-text versions of statements are also available online through an electronic bulletin board system and through the Internet:

### **NIH Information Center BBS**

(301) 480-5144

### **Internet**

*Gopher*

<gopher://gopher.nih.gov/Health and Clinical Information>

*World Wide Web*

<http://text.nlm.nih.gov>

*ftp*

<ftp://public.nlm.nih.gov/hstat/nihcdcs>



U.S. DEPARTMENT OF HEALTH  
AND HUMAN SERVICES  
Public Health Service  
National Institutes of Health  
Office of Medical Applications of Research  
Federal Building, Room 618  
7550 Wisconsin Avenue MSC: 9120  
Bethesda, MD 20892-9120

---

Official Business  
Penalty for private use \$300

BULK RATE  
Postage & Fees  
PAID  
DHHS/NIH  
Permit No. G763