

# FAILURES OF TOTAL HIP REPLACEMENT: A POPULATION-BASED PERSPECTIVE

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The authors are embarking on a federally funded study of the epidemiology and outcomes of revision total hip replacement in the US Medicare population. This paper reviews background information on the epidemiology and outcomes of revision total hip replacement. Our goal is to identify critical gaps in the published literature on rates and predictors of revision total hip replacement among patients who have had a primary THR.

## OVERVIEW

Osteoarthritis of the hip affects over four million persons in the US and results in over 200,000 primary elective total hip replacements (THR) per year.<sup>1-3</sup> Failure of the prosthesis is a costly and disabling complication, resulting in 37,000 revision hip replacements annually in the US.<sup>1</sup> At \$31,000 per case in hospital costs alone, these revision procedures cost the nation over one billion dollars annually. Revision THR is also potentially morbid, with two-to three-fold higher risks of mortality and major complications than primary THR,<sup>4, 5</sup> and less improvement in functional status than primary THR.<sup>6, 7</sup> The number of revision and primary THR surgeries performed in the US increased by over 50% from 1993-2004.<sup>1</sup> Thus, we can anticipate a growing burden of revision total hip replacements over the next decade, with attendant complications, disability and costs. However, our capacity to anticipate and reduce the number of THR failures is limited by a lack of critical data. Specifically, US population based rates of revision have not been determined and there are no US population based studies of risk factors for THR failure leading to revision. All US studies of THR failures and risk factors associated with failure have been performed in referral centers. There is no national total joint registry in the US and therefore there are no reliable estimates of the annual and cumulative rates and determinants of THR failure in the smaller hospitals that perform the vast majority

of THRs in the US.<sup>4</sup> As revisions are complex, resource intensive procedures, these data are crucial to ensure adequate care for patients undergoing revision THR and to reduce the risk of failures. These observations highlight the urgent need for population based studies to define the rate of failure leading to revision THR and to identify risk factors, especially those that are modifiable.

In this paper, we provide background on the epidemiology and management of osteoarthritis of the hip, including total hip replacement. We describe the utilization rates and outcomes of THR, with emphasis on the key outcome for this proposal -- failure of the prosthesis, leading to a revision procedure. We include data on the association between hospital and surgeon volume of THR and outcomes, including failure. The rates, mechanisms and management of THR failure are reviewed. We close by discussing the national total joint registries developed in Scandinavian countries to monitor failure of THR, and preliminary efforts in this country to mount such registries.

## PREVALENCE, RISK FACTORS AND BURDEN OF OSTEOARTHRITIS OF THE HIP

Osteoarthritis is the primary indication for 94% of total hip arthroplasties.<sup>4</sup> Approximately 30% of adults greater than age 65 in the US have radiographic evidence of hip OA (Kellgren and Lawrence grade 2, 3, or 4),<sup>2, 3</sup> while the prevalence of *symptomatic, radiographically-documented hip OA* is about 4% in this age group.<sup>3</sup> African-Americans appear to have a similar or even slightly higher prevalence of hip OA than whites.<sup>3</sup> Age, genetic predisposition in certain families,<sup>14</sup> congenital or developmental hip disorders, obesity, occupational exposure to heavy weight-bearing activities (e.g. farming) and jobs with bending and squatting are established risk factors for the development of hip OA.<sup>15-18</sup> The direct medical cost attributable to OA in the US exceeds \$15 billion per year.<sup>19-21</sup> In addition, persons with OA are two to four times more likely than those without OA to retire early, to report reduction in work hours or to be unable to find work due to illness.<sup>20</sup>

## NON-OPERATIVE MANAGEMENT OF OSTEOARTHRITIS

The management of hip OA<sup>22</sup> includes non-pharmacologic approaches such as patient education and self-help programs, social support, weight loss (if the patient is obese), assistive devices, and exercises aimed at stretching, quadriceps strengthening and aerobic fitness. Multiple pharmacologic therapies can be used including acetaminophen, topical analgesics, nonsteroidal anti-inflammatory drugs, COX-2 inhibitors, opioid analgesics and injections of corticosteroids or hyaluronic acid.

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These measures may reduce pain and improve functional status but do not slow the progression of cartilage loss and joint damage. Hence, many patients with hip OA ultimately must decide whether to elect surgical management. The safety of NSAID's and COX-2 inhibitors is under intense scrutiny, which may increase demand for surgery. The primary surgical option for advanced hip OA is total hip replacement. In one study, 36% of patients with established, symptomatic hip OA elected THR over five years of follow up.<sup>23</sup>

### **UTILIZATION OF TOTAL HIP REPLACEMENT IN OSTEOARTHRITIS**

In 2004, over 250,000 primary total hip replacements were performed in the US at a median in-hospital cost of about \$30,000 per case.<sup>1</sup> Sixty percent of these procedures were performed in patients over age 65,<sup>1</sup> and 94% were performed for osteoarthritis.<sup>4</sup> African-Americans and Hispanics receive THR at one-third the per capita rate of Whites in the US.<sup>5, 12, 24</sup> Over 40,000 revision THRs were performed in 2004, at an average in-hospital cost of \$33,000.<sup>1</sup> The total *inpatient* cost of primary and revision THR exceeds \$8 billion annually. Fifty percent of primary THR recipients are discharged to inpatient care facilities for further rehabilitation, and the remainder generally have rehabilitation services provided at home, adding another several billion dollars to the total national annual cost of THR.<sup>1</sup> The number of patients who undergo THR each year represents just a fraction of the total number who have severe lower extremity arthritis and who would be eligible and willing to have the procedure. For example, in Ontario twice as many persons over age 65 with hip or knee OA state that they are definitely willing to have joint replacement than the number that actually undergo the procedure.<sup>25</sup>

### **PROCEDURE VOLUME AND OUTCOMES OF THR**

In 1995, over one-third of primary THRs were done in hospitals that performed fewer than 25 cases per year (low volume centers) in the Medicare population.<sup>4</sup> This has important implications for outcomes. Surgeons and hospitals that perform a high volume of select surgical procedures have consistently been shown to have superior outcomes. These associations between volume and outcome have been documented across a range of cardiac, vascular and oncologic surgeries.<sup>26-28</sup> More specifically, higher hospital or surgeon volume has been associated with lower mortality following coronary artery bypass surgery,<sup>29</sup> congenital heart disease surgery,<sup>30</sup> coronary angioplasty,<sup>31-33</sup> carotid endarterectomy,<sup>34</sup> cancer surgery,<sup>35-40</sup> liver transplantation,<sup>41</sup> cataract implantation,<sup>42</sup> total knee replacement,<sup>43-45</sup> and medical care for myocardial infarction<sup>46</sup> and systemic lupus erythematosus.<sup>47</sup> Several studies on total hip replacement also showed inverse associations between hospital and surgeon volume and perioperative mortality and complications.<sup>4, 45, 48-50</sup> We have shown that high volume *surgeons* had approximately two-fold lower rates of dislocation, infection and early failure of the procedure following primary THR, and high volume *hospitals* had lower rates of mortality<sup>10</sup>

The mechanisms mediating the effects of hospital and surgeon volume on outcome have not been established,

although some hypotheses have been proposed. Higher volume hospitals may invest in equipment and programs that improve outcomes. The lower prosthesis failure and dislocation rates among high volume surgeons may reflect technical proficiency such as superior alignment of components and treatment of the soft tissue envelope. The effect of surgeon volume on mortality following revisions may relate to the duration of the procedure. In fact, the mean operative time for revision THR is 45 minutes longer if the procedure is performed by low volume surgeons than by high volume surgeons.<sup>8</sup>

### **OUTCOMES OF THR**

#### **PERIOPERATIVE AND SHORT TERM FUNCTIONAL OUTCOMES OF THR:**

Among Medicare recipients having primary THR across the US, the risk of death in the first 90 days following surgery is 1.0%, and the risk of pulmonary embolus is 0.9%.<sup>4</sup> Three percent of US Medicare recipients who have had THR experience dislocation and 0.2% have a deep joint infection during the first 90 postoperative days.<sup>4</sup> Functional outcomes are generally excellent following primary THR, with over 90% of patients experiencing significant pain relief and functional benefit in referral center series.<sup>51, 52</sup> *Revision THR* is followed more frequently by complications than primary THR, with risks of death, dislocation and infection of 2.5%, 8.3% and 1.0% respectively.<sup>4</sup> Revision THR is also associated with worse functional outcomes than primary THR, including greater use of walking support and more frequent limp.<sup>6, 7</sup>

#### **HISTORICAL SHIFT IN FOCUS TO LONG TERM OUTCOMES OF THR:**

During the early years of total hip replacement in the 1960s and early 1970s, research focused upon reducing the incidence of perioperative complications, particularly infection, dislocation and early technical failures. The next phase of THR research turned to optimizing the design of the implant, improving surgical technique, and refining rehabilitative strategies to improve pain relief and functional results. During the last decade attention has shifted to long term outcomes and, in particular, to implant failure due to mechanical loosening and osteolysis (immune-mediated periprosthetic bone resorption incited by wear particles.)<sup>53, 54</sup>

#### **TECHNICAL VERSUS PUBLIC HEALTH APPROACH TO IMPROVING THR OUTCOMES:**

Much current research on THR focuses on developing biomaterials for bearing surfaces to reduce wear debris and osteolysis, and thereby improve longevity of the prosthesis. Our own research over the last decade has attempted to complement these technical, biological and biomechanical approaches with a public health strategy. We seek methods of *optimizing the utilization of existing technologies* to improve outcomes – both overall and in select vulnerable populations.

### **FAILURE OF TOTAL HIP REPLACEMENT: MECHANISMS, MANAGEMENT AND EPIDEMIOLOGY.**

#### **FAILURE MECHANISMS:**

Total hip replacements may fail for a variety of reasons. Table 1 shows the relative frequency of a range of failure mechanisms for patients who had primary THR in the Swedish Hip Registry.<sup>55</sup> The prostheses can become *infected*, either by

direct inoculation of the joint at the time of the initial surgery, or by joint seeding during bacteremic episodes over longer term follow up. *Fracture* of a prosthetic component occurs rarely following primary THR. Incorrect alignment of the components and poor compliance with postural restrictions can lead to repeated *dislocations*. Suboptimal component design or positioning can lead to mechanical *loosening*. Repeated wear of the polyethylene or other materials can generate wear debris that incites osteolysis, with resorption of bone. Osteolysis is not distinguished from aseptic loosening in the Swedish Register data (Table 1).

**Table 1: Indications for revision THR in Swedish Hip Register**

| Reason               | N      | %   |
|----------------------|--------|-----|
| Aseptic loosening    | 10,610 | 75% |
| Deep joint infection | 948    | 8%  |
| Dislocation          | 810    | 6%  |
| Fracture             | 716    | 5%  |
| Technical error      | 425    | 3%  |
| Implant fracture     | 215    | 1%  |
| Other                | 357    | 4%  |

**CLARIFYING TERMS: “FAILURE” AND “REVISION”:**

Prosthesis failure is not synonymous with THR revision. Patients may have considerable osteolysis and loosening and yet have no symptoms.<sup>56</sup> Patients may also experience symptomatic, functionally-limiting loosening of the prosthesis but prefer to endure the pain than to have revision surgery. Patients with symptomatically loose prostheses may also have too many or too severe comorbid conditions to undergo the surgery safely. Thus, reported rates of radiographic loosening are higher than rates of revision.<sup>57</sup> This limitation notwithstanding, revision surgery is an unambiguous and specific endpoint of a failed prosthesis, whereas radiographic and symptomatic evidence of failure can be subtle and difficult to ascertain reproducibly. Thus, we will use revision surgery as our marker of failure. This convention is consistent with other large-scale studies of THR failure.<sup>55, 58-60</sup> We recognize the cumulative incidence of revision ascertained in the proposed study will underestimate the cumulative incidence of failed prosthesis. Further, by using revision as an endpoint, analyses of predictors may be biased.

**MANAGEMENT OF FAILED THR:**

Treatment depends on the mechanism of failure. Infected THR is treated urgently, typically with prosthesis removal and insertion of another prosthesis after about six weeks of antibiotic therapy. (In select circumstances, immediate replacement without delay may be indicated <sup>56, 61</sup>). When prostheses fail for any of the other reasons listed in Table 1, the patient may have the option of living with the pain and functional impairment associated with a failed prosthesis, or of proceeding with revision surgery. In a revision, one or both components are removed and replaced. More limited procedures can be done as well, such as change of a polyethylene liner. Revision THR

is technically demanding. Cases with extensive osteolytic bone loss may require substantial bone grafting. Generally, the decision to undertake revision is driven by use-related pain. But if massive osteolysis occurs in the absence of pain, revision may be advised while there is still sufficient bone stock to avoid a much more difficult revision in the future.<sup>56, 62</sup>

**OUTCOME OF REVISION SURGERY FOR FAILED THR:**

Revision surgery has a less favorable outcome than primary THR. Rates of adverse events occurring within 90 days of revision THR—including mortality (2.5%), dislocation (8.3%) and deep infection (1%)—are two- to five-times higher than following primary THR.<sup>4</sup> Furthermore, revision surgery is less successful than primary THR in relieving pain and improving functional status<sup>8</sup>. The risk of re-revision following revision THR exceeds that of revision following primary THR.<sup>56</sup> Thus, failure of THR and subsequent revision threatens patients with significant morbidity, mortality, and reduced quality of life. *Hence, efforts to prevent or postpone failure of primary THR merit high priority. Identifying risk factors, as we propose, would address this priority.*

**B.6.5. RATES OF LONG TERM FAILURE LEADING TO REVISION THR:**

**RATES OF THR FAILURE IN US REFERRAL CENTERS:**

Typically, reports of THR failure from referral centers involve a single surgeon and/or a single prosthesis type. As the studies are technically oriented, they often report rates of revision at the level of the specific component rather than at the patient level. In general, *referral centers report revision-free survival rates of over 90% after ten years of follow-up of primary THR.*<sup>57, 63, 64</sup>

**RATES OF FAILURE IN NATIONAL REGISTERS:**

Several countries, including Sweden, Norway, Finland, Denmark and Hungary have developed national THR Registers. The most extensive is the Swedish National Hip Arthroplasty Register,<sup>55</sup> which was initiated in 1979. The Register gathers information about every primary and revision THR done in each orthopaedic unit in the country. Revisions are linked to the primary procedure. More than 95% of all THRs performed in Sweden are reported to the Register.<sup>65, 66</sup> Data on surgical technique are collected at the hospital level. Thus all patients operated upon in a particular hospital are regarded as having had the same surgical approach and cementing technique.<sup>55</sup> Of the 185,000 THRs performed in Sweden between 1979 and 2000, 9% resulted in revision surgery, the majority of which were done for aseptic loosening, with or without focal osteolysis. In Sweden, the risk of revision following primary THR was about 1% per year for prostheses implanted in the 1980s but only 3% over ten years for prostheses implanted in the early 1990s. Thus, prosthesis survival is improving dramatically in Sweden.<sup>55</sup>

The Scandinavian Registers have improved the quality of care in their home countries. Several implant types yielding poor results have been identified and eliminated from practice because of these Registers. The Registers have also demonstrated that uncemented femoral components have had worse

prosthesis survival, on average than cemented components. This finding has resulted in a substantial reduction in the use of uncemented implants in Scandinavia.<sup>59, 67</sup> This finding is of particular importance because the use of uncemented prostheses, which was 27% in our 1995-96 THR Medicare sample, has increased steadily over the last decade in the US.

#### **DIFFERENCES BETWEEN SCANDINAVIAN REGISTER DATA AND US**

##### **DATA ON FAILURE OF THR:**

The Scandinavian Registers are relatively small and their findings are not readily generalized to North American practice. More THRs are performed in the US in two years than in the entire histories of the Swedish, Finnish and Norwegian Registers combined. Furthermore, since the Scandinavian countries are more homogeneous than the US with respect to race and socioeconomic status, the registries cannot examine these potential determinants of failure. Moreover, in Scandinavia THRs are not performed in very low volume centers as occurs frequently in the US. For example, in Norway just 10% of THRs are performed in hospitals with an annual volume of less than 35 cases, whereas 36% of cases in the US are performed in such low volume centers.<sup>4, 68</sup>

##### **EFFORTS TO LAUNCH A US TOTAL JOINT REGISTRY:**

Sweden, Norway, Finland, England, Canada and the province of Ontario have made major commitments to total joint registries. These efforts have sparked enthusiasm for the development of a US Total Joint Replacement Registry.<sup>69</sup> A national meeting held on this subject in 2001, jointly sponsored by NIH, AHRQ, FDA and the American Academy of Orthopaedic Surgeons, concluded that a total joint registry is a critical component of quality assurance and that the next step should be to examine the use of Medicare data for monitoring the outcomes of THR and TKR on a national level.<sup>70</sup>

##### **RISK FACTORS FOR LONG TERM THR FAILURE:**

Weight, age less than 45 and greater than 75, male sex and diagnosis of avascular necrosis appear to be important risk factors for prosthesis failure.<sup>71, 72</sup> (Body mass index appears less predictive, as weight better reflects mechanical load). However, the literature does not clarify the independent contributions of these factors to the risk of failure, nor of the underlying diagnosis or comorbidity. Because virtually all series are reported from single centers, the literature provides no insight into the role of hospital level factors such as procedure volume, teaching status and nurse to patient ratios, or surgeon level factors such as procedure volume, board specialization or years of experience. Furthermore, despite the voluminous literature on associations between socioeconomic status and race on a range of outcomes, the role these factors play in predicting failure of THR is unknown.

The Swedish Register confirms that patients younger than 55 and males have higher failure rates.<sup>55, 73</sup> It also documents improved outcomes associated with modern cementing techniques (femoral cement plugging, distal centralizer, pulsatile irrigation, vacuum mixing, cement pressurization<sup>55</sup>). The Norwegian Register documents higher failure rates for uncemented than for cemented femoral components.<sup>74</sup> The

Norwegian Register data also suggest that patients taking systemic steroids, former smokers and men who were more physically active are at higher risk for failure.<sup>58</sup> The role of physical activity is unclear. Of note, a recent case control study of failed total *knee* replacement found that physical activity level was not a risk factor for TKR failure.<sup>75</sup>

Thus, the literature on risk factors for THR failure points to some non-modifiable risk factors such as male sex and age and some modifiable factors such as weight, smoking, uncemented prosthesis, cementing technique, activity level and steroid use. (In fact, male sex may be a proxy for modifiable factors such as type and extent of physical activity). However, the literature is strikingly sparse, studies are generally underpowered, and in the US studies are reported exclusively from single referral centers.

At a more conceptual level, prior studies of long term THR failure have addressed select potential risk factors in the absence of a guiding, overarching conceptual model of THR failure. Our work is anchored by a multidimensional view of patient outcomes and quality of care. We propose that a combination of patient level clinical and sociodemographic variables, technical factors and surgeon and hospital characteristics act both independently and interactively to give rise to THR failures. This approach is reflected in our study hypotheses and analyses and will permit inferences that address quality of care and outcomes at several levels of potential intervention.

#### **SUMMARY: GAPS IN THE LITERATURE**

Advanced hip osteoarthritis is an increasingly prevalent and costly source of pain and disability. Until disease modifying therapies are developed and shown to be effective, many patients will experience progression of OA and opt for total hip replacement. THR is among the most successful interventions in medicine, but failures leading to revision are common, disabling and costly. The success of THR has been studied carefully in referral centers, but virtually nothing is known about the incidence and predictors of failure of primary THR in US community settings, where most of these procedures are performed. In particular, we know little about whether primary THRs are more likely to fail if they were performed in low volume centers or by low volume surgeons. Clinical, demographic and socioeconomic risk factors for THR failure are poorly established, as the US literature on risk factors is sparse and restricted to single center series. More reliable estimates of the rates and risk factors for failure of THR would 1) help to project the need for revision THR at a national level and in select patient subgroups; 2) point to potential interventions to reduce rates of failure leading to revision; and 3) provide patients and providers with the information they need to meaningfully discuss the full range of risks and benefits of THR, tailored to the patient-specific risk factors. Thus, there is an urgent need for a population-based study of the incidence and risk factors for failure of THR in the US.

We hope to be able to report in subsequent issues of this journal on steps our team has made toward addressing some of the key questions and research gaps identified in the paper.

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