Resurfacing Arthroplasty for Patients with Osteonecrosis

 Bernard N. Stulberg, M.D., Stephanie M. Fitts, Ph.D., Jayson D. Zadzilka, M.S., and Kathy Trier, Ph.D.

Abstract

The suitability of third-generation metal-on-metal hip resurfacing products for patients with a primary diagnosis of osteonecrosis has been debated. The preservation of femoral head bone stock for femoral prosthetic support is essential for the long-term stability of implants. A modern hip resurfacing system was implanted in 1148 hips as part of a United States multicenter investigational device exemption study. Of these, 116 hips had a preoperative diagnosis of osteonecrosis and were compared to 1023 hips with osteoarthritis. Survival rates were not significantly different (95.9% and 95.8% at 24 months for osteoarthritis and osteonecrosis respectively, \( p = 0.46 \)). Resurfacing arthroplasty for patients with osteonecrosis appears to be a reasonable alternative, taking into consideration implant size, patient gender, and size of femoral deficiency. Further characterization is needed to identify those specific patients with osteonecrosis for whom resurfacing arthroplasty would be appropriate.

While the goal of treatment for early osteonecrosis (ON) has focused on the preservation of the femoral head, especially in the young, active patient, later stages are typically treated with some form of arthroplasty. Hip resurfacing approaches have been used, with the recent debate centered on metal-on-metal (MOM) interfaces, which may be appropriate for the early collapse stages of ON. We have recently reviewed our experience thus far using current-generation MOM resurfacing. Given the present debate on the suitability of MOM hip resurfacing for patients with a primary diagnosis of osteoarthritis (OA) and ON, we undertook this analysis to compare the risk of revision for these diagnostic groups in a multicenter United States (U.S.) database of a third-generation MOM hip resurfacing system.

Materials and Methods

A U.S. multicenter study was performed under an investigational device exemption (IDE) from the Food and Drug Administration (FDA) to evaluate the performance of a third-generation metal-on-metal total hip resurfacing system (Cormet, Corin Ltd., Tampa, Florida). The system was comprised of a high carbon cobalt-chrome femoral component, with a diminutive stem and a highly polished bearing surface that mates with the acetabular component bearing within a tightly controlled tolerance for low-sliding resistance. The acetabular component was designed with a plasma-sprayed titanium surface, which was then sprayed with commercially pure hydroxyapatite. Two sets of external anti-rotational splines were designed to facilitate initial implant stability.

Between April 2001 and May 2006, 1148 hips were enrolled in the pivotal and continued access phases of the investigation. Subjects were enrolled at 12 sites across the U.S. after Investigational Review Board (IRB) approvals at each institution were granted. The surgery was performed by the investigator at each site, using a common surgical protocol. The vast majority were performed via the posterolateral approach. The acetabulum was reamed to the templated size, and the acetabular component was implanted by press fit. A neck-centering jig was used to place a pin in the femoral head in order to guide the femoral resurfacing reamer. The femoral component was cemented in the dome area only, with care being exercised not to cement around the stem.

Patients returned for postoperative clinic visits at 6 weeks, 6 months, 1 year, and yearly thereafter. The average...
follow-up time was 20 months as of the close of the database. Patients who experienced adverse events were seen, as needed, for assessment and treatment at visits in addition to the protocol defined timeframes. Radiographs, clinical evaluations (including a Harris hip score), and assessment for medical complications were undertaken at each patient visit.

An initial multivariate analysis of variance (MANOVA) model was constructed to identify patient factors indicative of increased risk of component revision for any cause. The factors included in the model were age, gender, weight, diagnosis, preoperative leg-length discrepancy, baseline Harris hip score, duration of symptoms, component size, investigative site, and inclusion in the site’s first 25 cases. Additional exploratory analysis was performed to attempt to answer the question, “Do subjects with ON have an increased risk of revision when compared to subjects with OA?” All analyses were performed using Statistical Analysis Software (SAS version 9, Cary, North Carolina).

**Results**

A primary diagnosis of ON was made in 116 hips (101 patients) by the surgeon. Fifteen were classified as Ficat stage I, 14 as stage II, 52 stage III, and 35 stage IV. The remaining subjects were diagnosed with either OA (n = 1023) or rheumatoid arthritis (RA, n = 9). Our initial multivariate analysis of variance for all 1148 procedures did not suggest diagnosis as a risk factor for an increased rate of revision. However, a site analysis demonstrated that one site had a significantly lower percentage of patients with diagnoses other than OA (4.6% for the one site vs 12.2% for all sites combined). When this site was excluded, diagnosis did become a significant predictor for revision.

The population was then divided by diagnosis and the OA and ON groups were compared, showing important differences in baseline characteristics. The ON group was younger, more prone to bilateral disease, and demonstrated their symptoms for a shorter period of time prior to surgical intervention. The baseline Harris hip score was indistinguishable between the groups. At the 2-year follow-up visit, the groups were comparable in mean Harris hip scores and the percentage of subjects having good or excellent results.

Evaluating survival of the prosthesis between groups showed that the two groups demonstrated remarkably similar survival estimates when failure was defined as the revision of any component for any reason. The Kaplan-Meier survival curves are shown in Figure 1. Examining the 24-month survival estimate shows a 95.86% survival for the OA group and a 95.9% survival for the ON group. The Wilcoxon p-value for this comparison is 0.46, indicating no true difference between the survival curves. We further evaluated the ON group by stage of disease (Ficat stages III and IV). Comparison of the component survival for this subgroup also showed no appreciable difference in survival between groups. The Ficat stage III and IV groups had an estimated 24-month survival of 96.1%, with a Wilcoxon p-value of 0.57. The reasons for revision across the groups also did not demonstrate significant differences between them, although some variations were noted (Table 1).

The ON group had a slightly greater incidence of femoral loosening as a reason for revision, and the OA group had a

### Table 1 Reasons for Revision in the Osteonecrosis and Osteoarthritis Groups

<table>
<thead>
<tr>
<th>Reason for Revision</th>
<th>Osteonecrosis (n = 116)</th>
<th>Osteoarthritis (n = 1023)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral neck fracture</td>
<td>3</td>
<td>18</td>
</tr>
<tr>
<td>Femoral loosening</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Acetabular loosening</td>
<td>—</td>
<td>8</td>
</tr>
<tr>
<td>Deep infection</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Dislocation</td>
<td>1</td>
<td>—</td>
</tr>
<tr>
<td>Total</td>
<td>8</td>
<td>35</td>
</tr>
</tbody>
</table>

![Figure 1](image-url) Kaplan-Meier survival curve of osteonecrosis (ON) and osteoarthritis (OA) populations. Note the survival estimates are very similar at 24-months postoperatively, and the log rank test gives a nonsignificant p-value.
higher rate of acetabular loosening. We tested the hypothesis that the reasons for revision were different between the two groups, using a Fisher’s generalized exact test and obtained a p value of 0.085, which indicates some marginal evidence for different reasons for revisions between the groups.

Discussion

This study produced the largest series of ON subjects consecutively enrolled as part of a multicenter investigation known to date. The multivariate analysis demonstrated variable results among centers with ON subjects. One center, for example, had a high revision rate but no revisions in subjects with ON. A diagnosis other than OA became a significant risk factor for revision when this center was excluded from the analysis. We hypothesized, therefore, that a diagnosis of ON would be a significant risk factor for revision and that the Kaplan-Meier survival curve for ON would be significantly different than the survival curve for OA at 24-months postoperatively. Careful analysis revealed that there was no difference in survival between these groups at 24 months. We could find no difference in survival based on surgeon-reported Ficat stages, and for which most surgeons used careful intraoperative analysis of lesion size and location to determine.

Early generation implant systems resurfaced the femoral head using a metal component and for the acetabulum used acetabular articular cartilage that is predisposed to degenerative change when only the femoral head is resurfaced.1

With the development of improved metallurgy, implant design, and manufacturing processes, third-generation metal-on-metal hip resurfacing devices have demonstrated promising short- to midterm clinical results and acceptable survival rates.6-8 Reported advantages include preservation of femoral bone stock, lower dislocation rates, pain relief, and easy conversion to total hip arthroplasty, if needed.

Beaulé and colleagues9 reported superior functional clinical outcomes with metal-on-metal hip resurfacing (56 procedures) in the treatment of ON, in comparison with hemi-arthroplasty (28 procedures). With an average postoperative follow-up of 4.9 years, the metal-on-metal resurfacing patients reported significantly higher UCLA (University of California, Los Angeles) scores (function and activity), higher Harris hip scores and higher SF-12 physical component scores. Fewer revisions were reported in the metal-on-metal group, but there was a higher incidence of radiological changes [patients also had higher SARI (surface arthroplasty risk index) scores than the average for the total group]. Mont and coworkers10 found excellent clinical results in a matched group of 42 patients with ON and 42 patients with OA (average 41 months postoperative). The ON and OA groups showed comparable survivorship curves, with no increased rate of femoral loosening in the ON group. Revell and associates11 reported overall survivorship of 93.2% (average of 6.1 years postoperative; range, 2 to 12 years) in a single-surgeon consecutive series of 73 patients, who received metal-on-metal hip resurfacing for end-stage ON of the femoral head. Two of four revisions (one additional hip was planned for revision) were for aseptic loosening of the femoral component, giving a femoral component survival rate of 97.3%.

Short-term results have demonstrated metal-on-metal hip resurfacing can be considered a safe and effective treatment for ON, but questions about longer term success have been raised. Are patients with a preoperative diagnosis of ON more likely to fail as a result of worsening of the ON under the prosthesis, leading to loosening or fracture? How does femoral head vascularity and secondary ON relate to femoral neck fracture, femoral head collapse, and femoral loosening? Reports in the literature on the analysis of retrieved metal-on-metal hip resurfacing implants reflect diverse conclusions.

Bogoch and colleagues12 analyzed six femoral head revision retrievals for evidence of ON and found that ON may complicate resurfacing arthroplasty in certain cases and may subsequently lead to femoral neck fracture or femoral component loosening. Little and coworkers13 reported on 13 revisions in a series of 377 metal-on-metal hip resurfacing procedures [femoral neck fracture (8); femoral loosening (3); other (2)]. ON was found under failed implants in 12 of 13 patients; however, none of the patients had histological evidence of ON in the femoral bone removed at the time of implantation. On the other hand, Howie and associates14 examined 72 retrievals to distinguish localized areas of ON from generalized ON, which normally follows an avascular incident involving most of the femoral head. Results suggested that the thickening of bone trabeculae, a fibrovascular marrow, and superficial necrosis of bone of the femoral head are not evidence of generalized ON caused by the procedure, but instead they are a result of remodeling changes. Morlock and colleagues,15 in an examination of femoral neck fracture retrievals, found that the pattern of fractures and histological results indicate that ON was not necessarily connected with endoprosthetic surgery. Most failures analyzed could probably be attributed to a learning curve effect. Beaulé and coworkers16 suggest that these varying results in the literature may be related to factors such as (but not limited to) differing definitions and dif-
ferentiation between generalized ON and localized necrosis due to cement heat generation, as well as resorption of bone at the cement interface as a result of polyethylene wear debris.

**Conclusion**

In carefully selected patients with ON and favorable lesion size, resurfacing arthroplasty appears to be a reasonable option. However, a more careful definition of the location and volume of lesions addressed would be necessary for a better definition of appropriate patients in this population. Patients with ON were not found to have higher revision rates than patients with OA in this large multicenter trial. Although an initial multivariate analysis did point to the inclusion of diagnosis as a prognostic indicator, this effect was not strong enough when analyzed alone to discriminate patients with an increased risk of early revision. This finding and the variable results among centers with ON subjects show that direct observation and evaluation of each patient is critical to the efficacy of resurfacing in the short term.

A constellation of patient factors, including the quality and condition of the bone in critical regions of the proximal femur, should be considered when evaluating resurfacing as an appropriate intervention. Many investigators have pointed to a learning curve when adopting hip resurfacing, whereby their results improve over time as they become more familiar with the treatment. Patient selection is a critical component, and this early report on patients with ON points to the fact that broad generalizations based on diagnosis or even Ficat staging of ON are not adequate to judge patient suitability for resurfacing arthroplasty.

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**Disclosure Statement**

Bernard N. Stulberg, M.D., is a paid consultant for Stryker Orthopaedics. Stephanie M. Fitts, Ph.D., is employed by Stryker Orthopaedics. Kathy Trier, Ph.D., is employed by Corin Ltd. Jayson D. Zadzilka, M.S., does not have a financial or proprietary interest in the subject matter or materials discussed.

**References**