Survivorship Analysis and Radiographic Outcome Following Tantalum Rod Insertion for Osteonecrosis of the Femoral Head

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Background: For early stages of osteonecrosis, preservation of the femoral head is the primary objective; however, there has not been a consensus on how best to achieve this goal. Core decompression alone is associated with a lack of structural support with inconsistent outcomes, whereas vascularized fibular grafting requires an extensive surgical procedure with high donor-site morbidity and prolonged rehabilitation. The adjunctive use of a porous tantalum implant offers the advantages of core decompression, structural support, minimally invasive surgery, and no donor-site morbidity. The purpose of this study was to assess the survivorship and to evaluate the clinical results and radiographic outcomes of hips in which osteonecrosis of the femoral head was treated with core decompression and a porous tantalum implant.

Methods: We evaluated fifty-four patients (sixty consecutive hips) in whom osteonecrosis of the femoral head was treated with core decompression and insertion of a porous tantalum implant. Fifty-two patients (fifty-eight hips) were available for follow-up at a mean of twenty-four months. All patients were sixty-five years of age or younger (mean age, thirty-five years). According to the classification system of Steinberg et al., one hip (2%) had stage-I disease, forty-nine hips (84%) had stage-II disease, and eight hips (14%) had stage-III disease. Outcome measures that were used included a limb-specific score (Harris hip score), radiographic outcome measures, and survivorship analysis with revision to total hip arthroplasty as the end point.

Results: Overall, nine hips (15.5%) were converted to total hip arthroplasty, including six with stage-II disease and three with stage-III disease. The overall survival rates were 91.8% (95% confidence interval, 87.8% to 95.8%) at twelve months, 81.7% (95% confidence interval, 75.8% to 87.6%) at twenty-four months, and 68.1% (95% confidence interval, 54.7% to 81.5%) at forty-eight months. The absence of chronic systemic diseases resulted in a survival rate of 92% at forty-eight months (95% confidence interval, 87.4% to 96.4%).

Conclusions: Treatment of early stage osteonecrosis of the femoral head with core decompression and a porous tantalum implant can be accomplished with a minimally invasive technique and no donor-site morbidity. The early clinical results show encouraging survival rates in patients who do not have chronic systemic disease, especially in association with early stage disease.

Level of Evidence: Therapeutic Level IV. See Instructions to Authors on jbjs.org for a complete description of levels of evidence.

Osteonecrosis of the femoral head is a multifactorial condition with several pathogenetic mechanisms leading to a final common pathway of ischemia with subsequent marrow-cell and osteocyte necrosis[1-3]. Osteonecrosis of the femoral head remains a difficult disease to treat because it typically affects young patients in their third to fifth decades of life and because, unfortunately, the natural history of symptomatic disease includes progressive articular incongruity and subsequent osteoarthrosis of the joint[2-4].

A number of different treatment algorithms have been

recommended, depending on the age and underlying diagnosis of the patient, the size and location of the osteonecrosis, the extent of involvement of the weight-bearing surface, whether the femoral head has collapsed, and the amount of head depression. Appropriate treatment modalities for early osteonecrosis of the femoral head (Steinberg stages I and II) include core decompression with or without bone-grafting or vascularized fibular grafting. The clinical results of core decompression have been inconsistent[5,6], with a substantial decrease in satisfactory results when a crescent sign or definitive femoral head collapse is present (Steinberg stage III or greater)[4,7,8]. The addition of nonvascularized bone-grafting with use of either a lightbulb[9] or trapdoor[10] technique can provide structural support to the subchondral plate; however, these procedures require extensive surgical dissection and hip dislocation with associated morbidity. Free vascularized fibular grafting for osteonecrosis of the femoral head has been reported to provide satisfactory pain relief and functional improvement, with the best results occurring in patients who have no subchondral collapse preoperatively[11-14]. Nevertheless, these are extensive surgical procedures with high rates of complication, including: (1) donor-site morbidity with harvesting of the fibula (motor weakness, sensory abnormalities, and ankle pain)[15,16], (2) the risk of proximal femoral fracture[17], (3) increased technical difficulty with future total hip arthroplasty[18], and (4) prolonged hospital stay and rehabilitation[11].

Porous tantalum is a biomaterial with a unique set of physical and mechanical properties. It has a high-volume porosity (>80%) with fully interconnected pores to allow secure and rapid bone ingrowth[19]. In addition, it has a modulus of elasticity similar to that of bone, which minimizes stress-shielding. The material is structural and has sufficient strength to allow physiological load-carrying capabilities in the manufactured implant[20]. Recent studies have suggested that the addition of bone marrow, growth factors, or bisphosphonates can augment bone formation around and within porous tantalum[21,22]. The combined use of a porous tantalum implant and core decompression for the treatment of osteonecrosis of the femoral head provides structural support to the subchondral bone but avoids the morbidity associated with vascularized fibular grafting or nonvascularized bone-grafting techniques. The purpose of the present study was to assess survivorship of hips treated with core decompression and a porous tantalum implant for osteonecrosis of the femoral head and to evaluate the clinical results and radiographic outcomes.

Materials and Methods

We performed a retrospective review of fifty-four patients (sixty consecutive hips) in whom a porous tantalum implant (Trabecular Metal; Zimmer Trabecular Metal Technology, Allendale, New Jersey) was inserted to treat osteonecrosis of the femoral head (Figs. 1-A through 1-D). The biomechanical properties of the porous tantalum implant have been previously described in detail[19,20,23]. All procedures were performed by a single surgeon (M.D.M.) between November 1, 2001 and September 15, 2005. Procedures were performed for symptomatic patients who had radiographically documented osteonecrosis of the femoral head without articular surface depression and who were sixty-five years of age or younger (mean age, thirty-five years). Two patients (two hips, 3%) were lost to follow-up early (at six weeks after the operation) because they were from remote provinces. Both patients had improvement in their symptoms and no evidence of clinical or radiographic complications. All patients received a comprehensive evaluation that included preoperative medical history, physical examination, and anteroposterior and lateral radiographs. The data recorded included age at presentation, gender, associated risk factors, and, for hips with more advanced disease, the presence of contralateral hip resurfacing or total hip arthroplasty. The initial stage and the extent of involvement of the femoral head were assessed radiographically according to the classification system of Steinberg et al.[24-27]. Outcome measures included Harris hip scores, radiographic staging of the hip, adverse events, and survival analysis, with total hip arthroplasty as the end point for failure. Patients who had persistent pain and limitation in function and who were not satisfied with the outcome following tantalum rod insertion were assessed by a single surgeon (E.H.S.) for conversion to total hip arthroplasty.

Demographics

Fifty-two patients (fifty-eight hips with tantalum implants) were available for follow-up at an average of twenty-four months (range, six to fifty-two months). Four patients (four hips) from remote areas had only radiographic follow-up (sent by local physicians). Thirty-five patients were men and seventeen were women. The average age at the time of the index procedure was thirty-five years (range, twelve to sixty-four years). Twenty-five patients (48%) had bilateral involvement, including six patients who received a porous tantalum implant bilaterally, eleven patients who received a porous tantalum implant on one side and had had a previous contralateral total hip arthroplasty or resurfacing procedure, and one patient who received a porous tantalum implant on one side and had a contralateral vascularized fibular grafting. As of writing, seven patients are awaiting treatment for the opposite hip. The associated risk factors included corticosteroid use in twenty-two patients (twenty-six hips), excessive alcohol consumption in two patients (two hips), none known in thirteen patients (fifteen hips), trauma in six patients (six hips), and other factors in nine patients (nine hips). Systemic lupus erythematosus was the reason for the use of steroids in nine patients (eleven hips). Evaluation of preoperative radiographs for the stage of disease according to the Steinberg classification indicated that one hip (2%) had stage-I disease, forty-nine hips (84%) had stage-II disease, and eight hips (14%) had stage-III disease.

Operative Technique

The procedure was performed with the patient in the lateral decubitus position with the affected hip prepared and draped freely. Fluoroscopy was used to project the planned trajectory of implant insertion onto the skin, and a 2.5-cm mid-lateral longi-

Fig. 1-A

Fig. 1-B

Fig. 1-C

Fig. 1-D

Preoperative anteroposterior radiograph (Fig. 1-A), postoperative anteroposterior radiograph (Fig. 1-B), and four-year follow-up anteroposterior (Fig 1-C) and lateral (Fig. 1-D) radiographs of the right hip of a forty-two-year-old woman with systemic lupus erythematosus and corticosteroid-associated osteonecrosis. A tantalum implant was used to treat stage-II osteonecrosis in the right hip. The patient had previously undergone total hip arthroplasty on the contralateral side, also to treat osteonecrosis. Comparison of the preoperative, postoperative, and follow-up radiographs shows no evidence of progression of osteonecrosis and no implant-related complications.

tudinal incision was made. The fascia lata and the vastus lateralis muscle were split in the direction of their fibers down to the lateral aspect of the proximal part of the femur. With use of fluoroscopic guidance, the guidewire was then placed into the center of the osteonecrotic lesion, typically in the anterosuperior portion of the femoral head. Core decompression, under fluoroscopic guidance and with use of three cannulated reamers (8, 9, and 10 mm), was then used to remove bone up to the subchondral level. The length of the guidewire was then measured, and the core-decompression hole was tapped. Next, the 10-mm porous tantalum rod was inserted under fluoroscopic guidance until the implant abutted the subchondral plate. The incision was closed in layers. Patients remained in the hospital overnight and were told to remain non-weight-bearing with use of crutches for six weeks. Patients were then started on a strengthening physiotherapy protocol and allowed to progress to full weight-bearing as tolerated.

Statistical Methods

Statistical analysis of the data was performed with use of Statistical Package for the Social Sciences (SPSS) software (version 13.0 for Windows; SPSS, Chicago, Illinois). The Student t test was used for the comparison of means for parametric scale variables in independent groups. Nominal variables

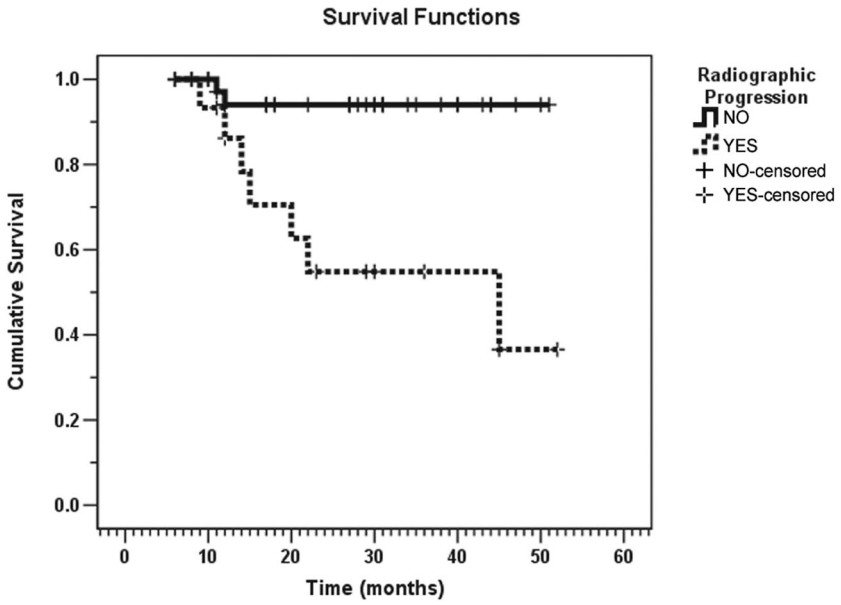

Fig. 2

Kaplan-Meier survivorship curve, stratified according to the number of hips that had radiographic signs of progression. The end point is revision to a total hip implant. The graph shows the proportion of porous tantalum implants that did not require revision. The estimated survival rates were 94% at forty-eight months for hips without radiographic progression (95% confidence interval, 89.9% to 98.1%) and 36.6% at forty-eight months for hips with radiographic progression (95% confidence interval, 19.1% to 54.1%) ($p = 0.002$).

were tested with use of the chi-square test or the Fisher exact test. A Kaplan-Meier survivorship analysis, with revision to total hip arthroplasty as the end point, was performed. A comparison of Kaplan-Meier curves for stratified factors was performed with the log-rank test (Mantel-Cox). Multivariate analysis was performed with use of the Cox proportional-

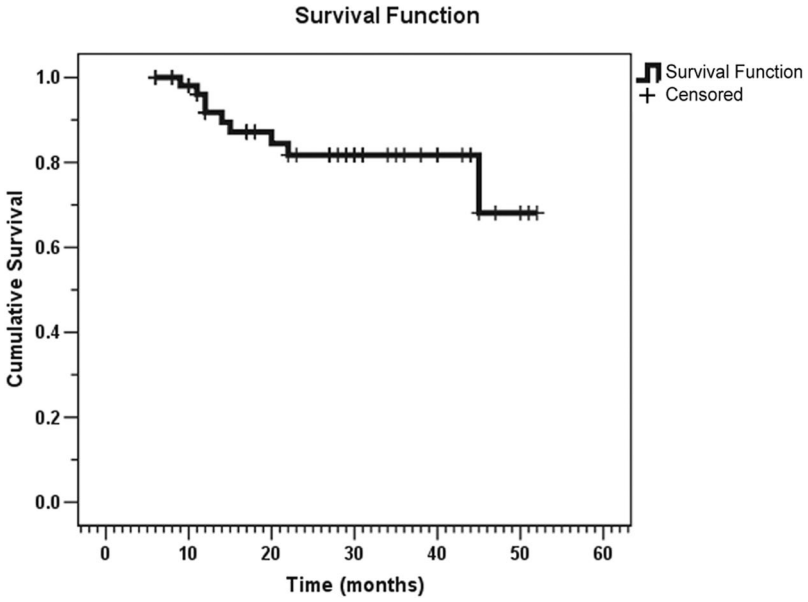

Fig. 3

Kaplan-Meier survivorship curve for all hips. The end point is revision to a total hip implant. The graph shows the proportion of porous tantalum implants that did not require revision. The survival rates were 91.8% (87.8% to 95.8%) at twelve months, 81.7% (75.8% to 87.6%) at twenty-four months, and 68.1% (54.7% to 81.5%) at forty-eight months. The number of remaining patients was: fifty-five at six months, forty at twelve months, thirty-two at eighteen months, twenty-eight at twenty-four months, twelve at thirty-six months, and four at forty-eight months. 95% confidence intervals are shown in parenthesis for each survival rate.

hazards model with censoring to identify the independent prognostic factors associated with clinical and radiographic failure. All tests were two-sided. The results were considered to be significant at $p < 0.05$.

Results

Hip Scores

The average postoperative Harris hip score for the fifty-four hips available for clinical evaluation at a mean of twenty-four months was 80 points (range, 55 to 96 points). Overall, nine hips were scored as excellent (91 to 100 points); eighteen hips, good (81 to 90 points); seventeen hips, fair (70 to 80 points); and ten hips, poor (<70 points). According to the preoperative stage of the disease, hips with stage-I or II disease (n = 47) at the time of surgery had a mean score of 81 points (range, 55 to 96 points [nine excellent, seventeen good, fourteen fair, seven poor]), whereas hips with stage-III disease (n = 7) had a mean score of 72 points (range, 60 to 90 points [one good, three fair, three poor]) ($p = 0.07$). With the numbers studied, an analysis of the hip scores according to associated risk factors (corticosteroid use, trauma, excessive alcohol intake, or idiopathic origin) did not show any significant difference with regard to the Harris hip scores; however, hips in patients with chronic systemic disease (systemic lupus erythematosus, Wegener granulomatosis, human immunodeficiency virus, or hepatitis) had a significantly lower average hip score (73 points; range, 55 to 95 points [one excellent, three good, five fair, six poor]) than hips in patients without chronic systemic disease (82 points; range, 60 to 96 points [eight excellent, fifteen good, twelve fair, four poor]) ($p = 0.01$).

Radiographic Progression

Radiographic progression occurred in sixteen of the fifty-eight hips (28%) after insertion of the porous tantalum implants. Thirteen stage-II hips showed progression on the preoperative radiographs: eight hips progressed to stage III, three hips showed flattening of the femoral head with depression (stage IV), and two hips showed joint-space narrowing (stage V). Two stage-III hips showed progression on follow-up radiographs: one hip progressed to stage V, and one hip showed advanced degenerative changes consistent with stage VI. Overall, seven of sixteen hips (43.8%) that had radiographic progression had conversion to a total hip arthroplasty, whereas only two of forty-two hips (4.8%) in patients without radiographic progression required conversion to a total hip arthroplasty (odds ratio = 15.8; 95% confidence interval, 2.7 to 87.7; $p = 0.001$). A comparison of Kaplan-Meier curves showed significantly higher survival rates ($p = 0.002$) for hips without radiographic signs of progression (94% at forty-eight months; 95% confidence interval, 89.9% to 98.1%) than in patients with radiographic signs of progression (36.6% at forty-eight months; 95% confidence interval, 19.1% to 54.1%) (Fig. 2).

Conversion to Total Hip Arthroplasty

Nine hips (15.5%) were converted to a total hip arthroplasty at an average of eighteen months (range, ten to forty-five months) after insertion of the porous tantalum implant. The primary indication for reoperation was pain in eight patients. One patient with chronic hepatitis had development of a deep infection and required a two-stage conversion to a total hip arthroplasty. The patients who had a revision included

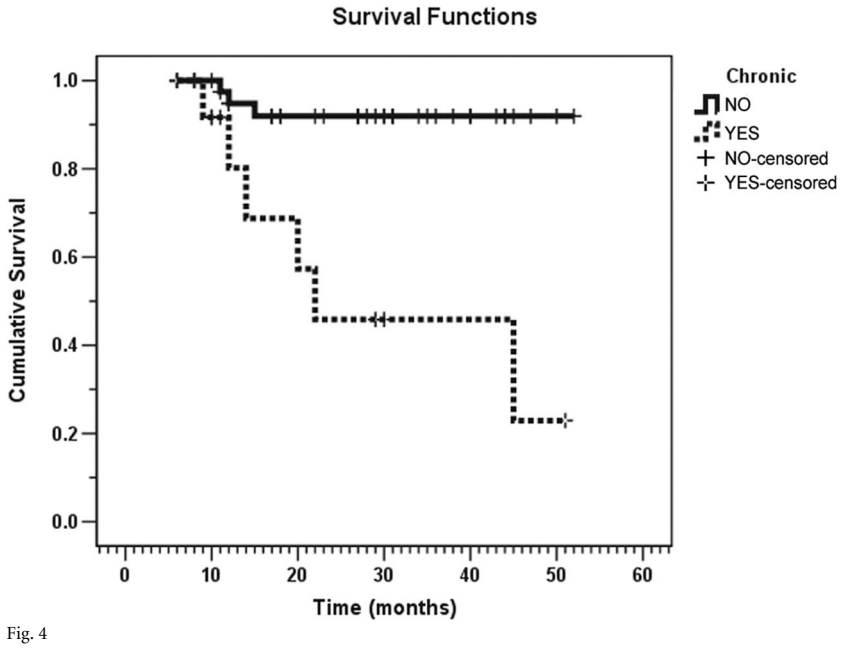

Fig. 4

Kaplan-Meier survivorship curve, stratified according to the number of patients with chronic systemic disease. The end point is revision to a total hip implant. The graph shows the proportion of porous tantalum implants that did not require revision to total hip arthroplasty. The estimated survival rates were 91.9% (95% confidence interval, 80.9% to 95.1%) at forty-eight months for hips in patients without chronic systemic disease, and 22.9% (95% confidence interval, 4.7% to 41.1%) at forty-eight months in patients with chronic systemic diseases ($p < 0.001$).

four men and five women (average age, thirty-six years; range, nineteen to sixty-four years). The preoperative associated risk factors were corticosteroid use for seven of these hips and none known for two hips.

Six (12%) of the hips with stage-II disease were converted to total hip arthroplasty, and three (38%) of the stage-III hips required conversion to total hip arthroplasty. The one stage-I hip did not need a total hip arthroplasty. The Kaplan-Meier survivorship analysis for all hips (Fig. 3) showed that the probability for not requiring revision to total hip arthroplasty after insertion of a porous tantalum implant was 91.8% (95% confidence interval, 87.8% to 95.8%) at twelve months, 81.7% (95% confidence interval, 75.8% to 87.6%) at twenty-four months, and 68.1% (95% confidence interval, 54.7% to 81.5%) at forty-eight months. Six of fifteen hips (40%) in patients with chronic systemic disease (systemic lupus erythematosus, Wegener granulomatosis, human immunodeficiency virus, or hepatitis) required conversion to total hip arthroplasty, whereas only three of forty-three hips (7%) in patients without chronic systemic disease required conversion to total hip arthroplasty (odds ratio = 8.9; 95% confidence interval, 1.9 to 42.4; $p = 0.006$). A comparison of Kaplan-Meier curves showed significantly higher survival rates ($p < 0.001$) for hips in patients without chronic systemic diseases (91.9% at forty-eight months; 95% confidence interval, 80.9% to 95.1%) than in patients with chronic systemic diseases (22.9% at forty-eight months; 95% confidence interval, 4.7% to 41.1%) (Fig. 4). In addition, in comparison with stage-II hips, there was a trend for stage-III hips to more likely require conversion to total hip arthroplasty ($p = 0.18$). With regard to underlying risk factors, there was a trend toward worse survival rates for hips with corticosteroid-induced osteonecrosis than for hips with idiopathic or other causes of osteonecrosis ($p = 0.10$). Four of eleven hips (36%) in patients with systemic lupus erythematosus required conversion to total hip arthroplasty, whereas only five of forty-seven hips (11%) in patients without systemic lupus erythematosus required conversion (odds ratio = 4.8; 95% confidence interval, 1.03 to 22.4; $p = 0.05$). With the numbers studied, no significant differences were found among the survivorship curves when stratified for bilateral disease ($p = 0.57$), age greater than fifty years ($p = 0.78$), and gender ($p = 0.20$).

The Cox proportional-hazards model revealed that chronic systemic disease was an independent prognostic factor related to conversion to total hip arthroplasty (hazard ratio, 4.5; 95% confidence interval, 1.03 to 19.79; $p = 0.046$). However, in the univariate or multivariate analyses, with the numbers available for study, no significant relationship was found between conversion to total hip arthroplasty and such factors as corticosteroid use, age over fifty years, gender, or bilateral disease. In addition, the use of corticosteroids was found to be an independent predictor of radiographic progression, regardless of the stage of disease (hazard ratio, 5.35; 95% confidence interval, 1.49 to 19.24; $p = 0.01$).

Complications

Complications included one case of superficial infection treated successfully with oral antibiotics, one case of deep infection managed with a two-stage conversion to a total hip arthroplasty, and one case of trochanteric bursitis.

Discussion

There has not been a consensus on how best to reduce symptoms and slow the progression of osteonecrosis of the femoral head. Several studies have shown that nonoperative treatment in symptomatic patients with early stage disease results in poor outcomes with progressive collapse in up to 80% of patients[5,6]. Numerous treatment algorithms have been proposed for early stage osteonecrosis of the femoral head. The most common procedures include core decompression alone or in combination with a structural vascularized fibular graft or one of several nonvascularized bone-graft techniques. Unfortunately, the efficacy of core decompression has varied markedly. Stulberg et al. showed that core decompression was successful in approximately 70% of hips on the basis of Harris hip scores[5]. In contrast, Koo et al., in a randomized clinical trial, reported radiographic signs of progression in 72% of patients treated with core decompression, and the majority of those hips required conversion to a total hip arthroplasty[6]. In a comprehensive literature review of twenty-four studies (1166 hips) that reported on the clinical outcome after core decompression, Mont et al. demonstrated an overall satisfactory clinical result in 64% of hips after an average of thirty months from core decompression[4]. Scully et al. reported that the rate of conversion to total joint arthroplasty after vascularized fibular grafting was significantly lower than after core decompression in hips that had stage-II or III disease. The survival rates, at fifty months, for hips that had stage-II disease were 65% after core decompression and 89% after vascularized fibular grafting. In hips that had stage-III disease, the rates of survival were 21% after core decompression and 81% after vascularized fibular grafting[12]. Recently, Tsao et al. reported favorable early clinical results in a multicentered investigational device exemption study of 113 porous tantalum implants in ninety-eight patients[23]. With revision to total hip arthroplasty as the end point, the overall survival rate for all stage-II hips (n = 93) was 72.5% at forty-eight months. The early results of the present study support the results of other studies, which indicate that, in patients without chronic systemic disease, hips treated with a porous tantalum implant have similar or better survival rates (92% at forty-eight months; 95% confidence interval, 87.4% to 96.4% in our study) than hips treated with core decompression and vascularized fibular grafting.

Although vascularized fibular grafting has shown promising results in young patients with osteonecrosis of the femoral head, there are several potential concerns: an extensive surgical procedure, increased donor-site morbidity[15,16], prolonged rehabilitation with protected weight-bearing for three to six months, and the risk of proximal femoral fracture[17]. Our study has shown that insertion of the porous tantalum implant can be performed safely and effectively through a minimally invasive technique (2.5-cm incision)

with no associated donor-site morbidity and minimal local complications. In addition, the patients who had the minimally invasive technique recovered more quickly than the patients of other studies who had vascularized fibular grafts; our patients required only a single overnight hospital stay followed by six weeks of non-weight-bearing walking with crutches.

Several studies have examined the prognostic factors associated with progression of collapse and subsequent osteoarthrosis despite operative intervention for osteonecrosis of the femoral head. Numerous studies have found that the results of core decompression[4,6-8,12,28-30] and vascularized fibular grafting[11-13] were substantially worse when there had been collapse of the femoral head preoperatively. Although we had a limited number of hips with preoperative collapse in our study, our results suggested a trend toward worse survival rates in stage-III hips compared with stage-II hips.

Another important factor in patient selection has been the underlying associated risk factors for the osteonecrosis. The results of several studies have suggested that outcomes are worse for patients who have corticosteroid-associated osteonecrosis[31-35]. Bozic et al.[29] demonstrated an independent relationship between the use of corticosteroids and survival of the hip in their survival analysis of hips that were treated with core decompression for osteonecrosis. In agreement with these studies, the present study identified the use of corticosteroids as an independent prognostic factor for radiographic progression, regardless of the stage of the disease.

The overall survival rate for all hips with a porous tantalum implant was 68.1% at forty-eight months. However, further analysis revealed that two-thirds of the hips that required conversion to total hip arthroplasty were in patients with chronic systemic diseases. In contrast, Garberina et al. reported that, in patients with systemic lupus erythematosus, the results of vascularized fibular grafting at a minimum duration of follow-up of two years are similar to those in patients without this diagnosis[36]. Although we were unable to show a statistically significant difference between the overall survival rates for hips stratified according to the diagnosis of systemic lupus erythematosus, the odds of requiring conversion to total hip arthroplasty were almost four times higher in patients with systemic lupus erythematosis than in patients without that disease. A comparison of the survivorship curves with hips stratified according to chronic systemic disease revealed significantly improved survival rates at forty-eight months (91.9%; 95% confidence interval, 87.4% to 96.4%) in the absence of chronic systemic disease. Furthermore, the Cox proportional-hazards model identified chronic systemic disease as an independent prognostic factor for failure and conversion to total hip arthroplasty.

The high failure rates in patients with chronic systemic disease may result from multiple concurrent vascular insults (vasculitis, hyperlipidemia, or thrombosis) and impaired bone metabolism. Systemic lupus erythematosus, Wegener granulomatosis, and human immunodeficiency virus may have effects on bone from associated vasculitis or antibody-mediated thrombosis[31,33,37]. In addition, these diseases often require ongoing management with corticosteroids, which may further potentiate the osteonecrosis. Furthermore, patients with chronic systemic disease often have bone-mineralization defects and osteoporosis with poor bone quality. These underlying factors may present a poor milieu for healing and prevention of collapse after porous tantalum-rod insertion and may explain the higher failure rate in this subset of patients. We believe that it is important to discuss with these patients the more guarded prognosis following insertion of porous tantalum implants.

The treatment of early stage osteonecrosis of the femoral head with core decompression and a porous tantalum implant can be accomplished with a minimally invasive technique, no donor-site morbidity, and few major device-related complications. For patients who do not have chronic systemic disease, and especially for those with early stage disease, the early clinical results from our study show encouraging survival rates and a delay in or prevention of progressive articular collapse in hips that are treated with a porous tantalum implant for osteonecrosis of the femoral head. ■

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