The Journal of Arthroplasty Vol. 14 No. 6 1999

Normalized and Proportionalized Cemented Femoral Stem Survivorship at 15 Years

William L. Jaffe, MD, and Christopher A. Hawkins, MD

Abstract: We reviewed the clinical and radiographic results of a series of 215 consecutive hip arthroplasties in which a normalized, proportionalized, cemented femoral component was implanted. This component design may encourage more efficient force transmission from prosthesis to cement to bone and lessen hoop stresses and resultant interface failure. A total of 127 hips in 103 patients with a follow-up of 13 to 17 years (average, 14.8 years) were available for evaluation, which included survivorship analysis. An aseptic failure loosening rate of 3.9% at 15 years for this stem favorably compares with other reported series of first-generation and second-generation stems at similar follow-up. Excluding the 8 stems placed in varus, of which 3 required revision (failure rate, 37.5%), the series has a failure rate of 1.6%. **Key words:** normalized, proportionalized, cemented, hip arthroplasty, survivorship.

As the average life span has increased and hip arthroplasty is performed in younger patients, consideration of long-term survival for total hip replacements has become of paramount importance. Because of the frequent modification of component designs, specifically with regard to the femoral component, reports of long-term outcome studies remain infrequent. This study provides the 15-year average follow-up of a femoral component whose design features a normalized (stepped taper) configuration and proportionalized dimensions. A previous report of the 10-year experience with this stem is published [1].

Materials and Methods

During the 4 years from January 1980 to January 1984, 184 patients underwent 215 consecutive cemented hip arthroplasties using a normalized, proportionalized cobalt-chromium femoral component (Fig. 1). Preoperative evaluations were performed for all patients by the senior author (W. L. J.) using the d'Aubigne and Postel rating system [2]. This system allows the variables of pain, function, and motion to be rated with a score of 0 to 6 points for each category.

All surgery was performed with the patient supine, through a transtrochanteric lateral approach. Cement was used in all cases, and no cement restrictors were employed during the first 3 years. Hand packing of the canal was routine in all cases, and in no case was either centrifugation or vacuum mixing used in the preparation of cement. The postoperative regimen included intravenous dextran for thromboembolic prophylaxis, removal of closed suction drains after 24 hours, and antibiotic prophylaxis for 48 hours.

For clinical follow-up, the senior author scored the hips using the d'Aubigne and Postel system. For radiographic follow-up, anteroposterior and lateral films were obtained at each annual visit. These films were evaluated for evidence of loosening (radiolucencies, cement fragmentation, or settling of the stem), fit and fill, component position, status of the

From the Department of Orthopaedic Surgery, New York University–Hospital for Joint Diseases, New York, New York.
Submitted September 30, 1998; accepted December 16, 1998.
Reprint requests: William L. Jaffe, MD, Department of Orthopaedic Surgery, New York University–Hospital for Joint Diseases, 301 East 17th St, New York, NY 10003.

0883-5403/99/1406-0011$10.00/0

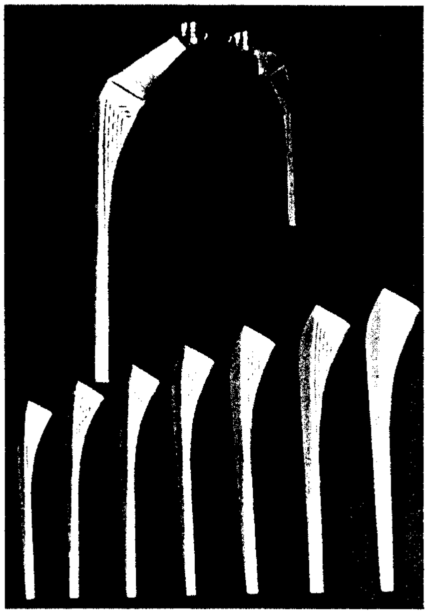

Fig. 1. Series of stems used in this study, demonstrating size variability and normalization (Osteonics, Allendale, NJ). The curved proximal lateral geometry was changed to a straight-back style in the last 11 months of the study to permit a more uniform cement mantle and to fill an area of the canal previously filled with cement.

trochanteric osteotomy, femoral stem fracture, and heterotopic ossification.

The study began with 215 hips in 184 consecutive patients. For the 10-year published data, 173 hips in 148 patients were available for review. For the present study, 127 hips in 103 patients were available for review. Follow-up periods for the present study ranged from 156 to 194 months (average, 176.1 months). Of the hip arthroplasties, 46 were in men, and 81 were in women; their average age at surgery ranged from 20 to 80 years (average, 60 years). A total of 74 were right hips, and 53 were left. Average patient height was 165.1 cm (range, 114.3 to 203.2 cm). Average patient weight was 73.9 kg (range, 24.9 to 136.1 kg).

Of the 215 index cases, 170 were primary arthroplasties, and 45 were revisions. The preoperative diagnoses in the primary cases included 126 osteoarthritis (74.1%), 20 avascular necrosis (11.8%), 13 inflammatory arthritis (7.6%), 7 posttraumatic arthritis (4.1%), and 4 developmental dysplasia (2.4%). The 45 revisions included 23 for failed total hip arthroplasty (51%), 10 for failed hemiarthroplasty (22%), 10 with previous internally fixed hip fractures (22%), and 2 for failed proximal femoral osteotomies (5%).

Results

Patient evaluation at latest follow-up visit was compared with preoperative values for each hip. Improvement was noted in pain, function, and motion of the operated hip. The average hip scores were improved as follows: pain, 3.0 to 5.9; function, 2.9 to 5.5; and motion, 3.3 to 5.5. Postoperatively, all cases were evaluated for canal fill at the junction of the proximal and middle thirds of the stem using anteroposterior radiographs and comparing the width of the prosthesis to the width of the medullary canal at this level. The range of fill was 35% to 89% (average, 64%). All stems were evaluated with regard to position in the femoral canal. Of the stems, 143 (67%) were in neutral, 63 (29%) were in valgus, and 8 (4%) were in varus. Originally, a valgus position was favored during the femoral component placement; later in the series, a neutral position became the goal. The 8 stems placed in varus were technical errors. Cortical hypertrophy was noted in 15% of cases at longest follow-up, primarily at Gruen zone 4 at the tip of the stem.

At an average follow-up of 12 years, 7 of 147 available hips (4.7%) showed radiographic evidence of aseptic loosening. No additional cases of loosening were noted at 15 years, and 2 of the original stems noted to be loose at 12 years were in patients who died before requiring revision. At 15 years, 5 of 127 available hips (3.9%) were radiographically loose. These 5 patients developed symptomatic loosening requiring revision, yielding an aseptic loosening failure rate of 3.4% at 12 years and 3.9% at 15 years. Of the 8 stems placed in varus, 3 eventually required revision for aseptic loosening (failure rate, 37.5%). Excluding the varus stems from the study results in a failure rate of 1.6% at 15 years. All 5 cases of aseptic loosening with cement failure occurred in young, active, and obese patients. Two of these failures were in cases of avascular necrosis (failure rate, 10%), 1 in inflammatory arthritis (failure rate, 7.7%), 1 in osteoarthritis (failure rate, 0.8%), and 1 among the 45 revisions (failure rate, 2.2%). For failures with avascular necrosis preoperatively, 1 revision was performed at 6 years and the second at 8 years postoperatively. Both the failed inflammatory arthritic hip and the failed revision hip came to surgery at 9 years postoperatively, whereas the 1 failure among the osteoarthritic group was revised at 10 years postoperatively.

Intraoperative Complications

There was 1 case in which the femoral cortex was perforated intraoperatively. This perforation occurred during a revision at the time of cement removal from the femoral canal. A long-stem component was successfully employed to bypass the defect. The intraoperative complication rate was 0.5%.

Early Postoperative Complications (Within 6 Weeks)

The overall rate of early postoperative complications was 10%. Most of these were nonspecific medical problems (10 cases, 5%). Complications related to the surgical procedure included 3 dislocations, 3 cases of trochanteric wire breakage, and 3 superficial wound infections. These infections were treated with antibiotics during hospitalization and had all resolved before discharge. There were no cases of deep infection. One patient developed separation of the osteotomized greater trochanter, and another suffered an ipsilateral femoral fracture in a motor vehicle accident.

Late Postoperative Complications

Sixteen patients (9%) developed painless heterotopic bone formation. Two of these patients had limited hip motion. Twelve patients had trochanteric wire breakage, and 2 had nonunion of the greater trochanter, all of which were asymptomatic.

Discussion

Survivorship of cemented total hip arthroplasty has become a critical issue for the orthopedic surgeon. As the population ages, a greater number of individuals have predictable survival many decades beyond the onset of degenerative osteoarthritis. Additionally, the excellent functional results of total hip arthroplasties in younger patients require a better appreciation of the predictable survival rates for hip replacements as well as the factors that influence survival.

Failure of the femoral component in a cemented total hip replacement most likely begins at the prosthesis–cement interface [3]. Mechanical factors cause debonding of the cement–metal interface and create stresses in the cement mantle, which are most concentrated proximally and at the tip of the stem. These stresses lead to fracture of the cement mantle, loss of component stability, and ultimately bony resorption through a biologic process [3].

Proportionalization

Three-dimensional finite-element analysis of femoral component stem designs by Crowninshield et al. [4] demonstrated that increasing the cross-sectional area of a stem decreased the forces within the implant as well as the surrounding cement mantle. Beckenbaugh and Ilstrup [5] observed that patients with large medullary canals (in which stem width at the midportion was less than half the femoral canal width) had a 2.5 times increased incidence of femoral component loosening compared with patients with more complete canal filling components. In a similar study by Ebramzedah et al. [6], it was observed that stems which filled more than half of the canal at a 7-cm distance from the collar had a significantly lower risk for progression to loosening and failure. The proportionalized prosthesis, which provides for a more complete fill of the femur, improves stress distribution to the cement mantle. Developed through an anthropometric study of various sized human femora, this stem design addresses the directly proportional relationship between the dimensions of femoral length, head diameter, neck length, and head offset [7]. As larger stems are used, the cross-sectional diameter and overall length increase (Fig. 2).

Normalization

The anterior and posterior surfaces of the proximal one third of the femoral stem are macrostructured with perpendicular cuts to create *normalized* force transmission. This surface design results in the direction of weight-bearing forces perpendicular to the longitudinal axis of the femur and discourages failure from cement fracture caused by hoop stresses (Fig. 3) [8]. Stauffer [9] found that the most common mechanism for femoral loosening in his series of hip arthroplasties was cement failure secondary to hoop stresses. Gruen et al. [10] noted that cement fractures more commonly occurred along the lateral or tension side of the prosthesis rather than the medial or compression side. Finite element analysis has shown that once slipping occurs at the cement–implant interface, previously existing compressive forces are converted to tensile stresses [10]. Methyl methacrylate bone cement has excellent compressive strength but is inadequate in flexural or tensile strength [11]. Cyclic and static bench testing revealed that cemented tapered pins with circumferential normalized surface enhancement had a 208% increase in the force required to cause interface failure compared to the force required to cause interface failure in cemented tapered pins of the same design without normalization. In the same study comparing cemented femoral stems with and without normalized enhancement on the anterior and posterior surfaces of the proximal third, there

Fig. 2. Radiographs taken at the same focal length of the smallest (14-year follow-up) and the largest (15-year follow-up) stems in the series. Case EM shows the curved proximal lateral geometry, and case JK shows the straight-back stem.

was a 66% increase in the force required to cause interface failure with the normalized design [8].

Long-Term Results

Reviewing the literature, there is a dearth of articles addressing survivorship of cemented hip arthroplasties beyond 10 years, and most of these studies report on first-generation Charnley prostheses. Charnley stems inserted with first generation cementing techniques demonstrate varied survivorship results among several series. Sochart and Porter [12] reported on Charnley arthroplasties with an average follow-up of 20 years. In their series, 23% of the stems required revision by 20 years, and the survivorship of these implants showed a decline from 93% at 10 years to 76% at 20 years. Similarly, Devitt et al. [13] reported that 16% of their Charnley hip arthroplasties required revision of the femoral component at 20 years with a survivorship probability of 79% for the stems at 20 years. Wroblewski et al. [14], using revision for aseptic stem loosening as an endpoint, reported a 94% survivorship rate at 17 years when 63 hips were available for study from an initial series of 441. Excellent survivorship rates were reported by Callaghan et al. [15] in a series in which 6% of femoral stems required revision for aseptic loosening at 15 years, which increased to 11% at 25 years. Far poorer results were found in a series of Charnley-type stems reviewed by Dorr et al. [16], in which 49% of the femoral components had undergone revision for aseptic loosening at 16 years (Fig. 4).

Survivorship studies of newer stem designs implanted with improved cementing techniques are infrequently reported. Kay et al. [17] published their 15-year follow-up of second generation stem designs (primarily T28 and TR28) and noted a 1.3% probability of revision in patients who were older

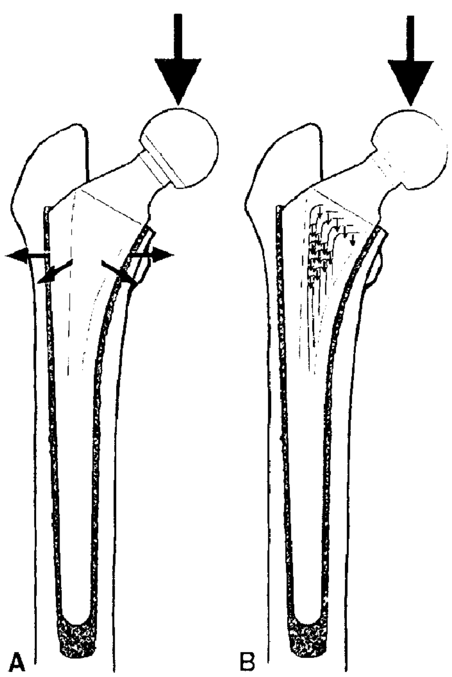

Fig. 3. Diagram of cemented smooth stem (A) and normalized stem (B) with transmission of weight-bearing forces to hoop stresses (A) or longitudinal forces (B).

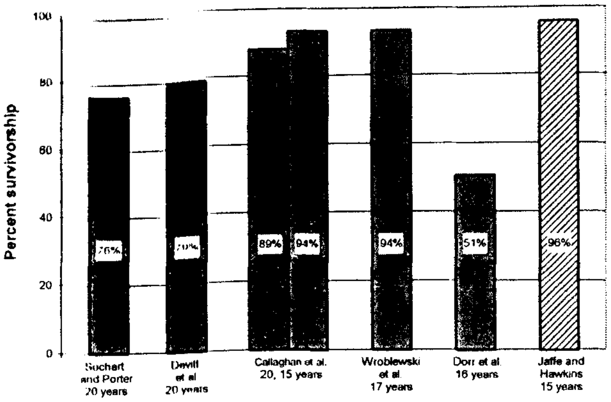

Fig. 4. Comparison of reported survivorship rates of first-generation cemented stems at 15 years or longer.

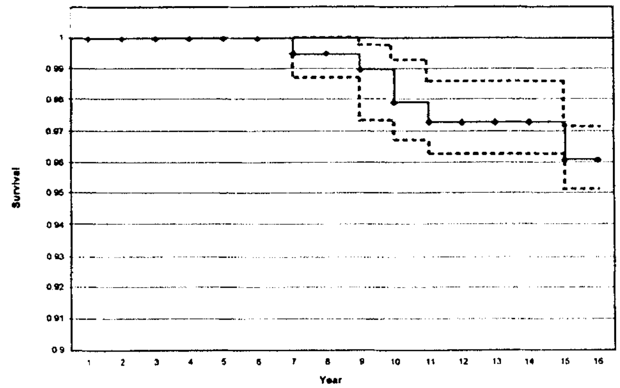

Fig. 6. Kaplan-Meier survivorship curve with aseptic loosening of the femoral component as the endpoint.

than 60 years of age at the time of arthroplasty, but the failure rate at 15 years was 18% when age at the time of surgery was blinded. Shinar and Harris [18], in a 15.5-year follow-up series of cemented second-generation stems inserted after failed femoral osteotomies, noted an 89.5% survivorship rate with femoral revision for aseptic loosening as the endpoint but an overall loosening rate for femoral prosthesis of 21.1% (Fig. 5). Devitt et al. [13] noted a revision rate of 35.7% for stems in varus, 12.7% for stems in neutral, and 8.5% for stems placed in valgus. These rates are similar to those in our series, supporting the suggested biomechanical benefits of a neutral or valgus position. In contrast, the series of hips reported by Kay et al. [17] showed no correlation between component position and revision rates. Of the prostheses available for follow-up in Wroblewski's series [14] at 13.5 years, 11% of stems in valgus position required revision for aseptic loosening compared to 1.5% of stems in neutral.

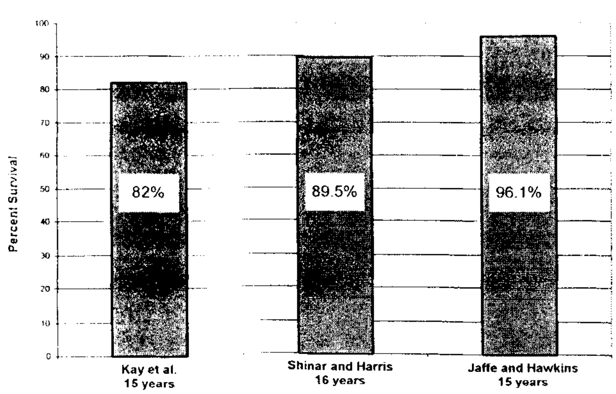

Fig. 5. Comparison of reported survivorship rates of second-generation stems at 15 years or longer.

Although the methods for calculating survivorship rates of the stems differ among these studies, it is clear that an aseptic failure loosening rate of 3.9% at 15 years for our series favorably compares with the previously reported loosening rates for cemented femoral components. In our study, a Kaplan-Meier survivorship analysis [19,20] with 95% confidence intervals demonstrated a 96.1% ± 5% probability of retaining the femoral component at 15 years (Fig. 6). Our series included patients undergoing primary and revision hip arthroplasty and with a wide range of age and activity levels, avoiding the bias of series limited to older, less active patients with primary arthroplasties. Such a review of long-term results for a second-generation cemented femoral component may serve as a future basis of comparison with uncemented femoral components and may help determine the optimal prosthetic choice for younger or more active individuals who require hip arthroplasty.

References

1. Jaffe WL, Jarolem KL: Normalized and proportionalized cemented femoral stem designs. J Arthroplasty 10S:39, 1995
2. D'Aubigne RM, Postel M: Functional results of hip arthroplasty with acrylic prosthesis. J Bone Joint Surg Am 36:451, 1954
3. Jasty M, Maloney WJ, Bragdon CR, et al: The initiation of failure in cemented femoral components of hip arthroplasties. J Bone Joint Surg Br 73:551, 1991
4. Crowninshield RD, Brand RA, Johnston RC, Milroy JC: An analysis of femoral component stem design in total hip arthroplasty. J Bone Joint Surg Am 62:68, 1980
5. Beckenbaugh RD, Ilstrup DM: Total hip arthroplasty: a review of 333 cases with long follow-up. J Bone Joint Surg Am 60:306, 1978

6. Ebramzadeh E, Sarmiento A, McKellop HA, et al: The cement mantle in total hip arthroplasty. J Bone Joint Surg Am 76:77, 1994
7. Averill RG, Pachtman N, Jaffe WL: A basic dimensional analysis of normal human proximal femora. Presented at the eighth annual Northeast Bioengineering Conference, Massachusetts Institute of Technology, Cambridge, 1980
8. Pugh J, Averill R, Pachtman N, et al: Prosthesis design to resist loosening: stress normalization. Presented at the 27th annual meeting of the Orthopaedic Research Society, Las Vegas, 1981
9. Stauffer RN: Ten year follow-up study with particular reference to roentgenographic loosening of the components. J Bone Joint Surg Am 64:983, 1982
10. Gruen TA, McNiece GM, Amstutz HC: Modes of failure of cemented stem-type femoral components. Clin Orthop 141:17, 1979
11. Jaffe WL, Rose RM, Radin EL: On the stability of the mechanical properties of self-curing acrylic bone cement. J Bone Joint Surg Am 56:1711, 1974
12. Sochart DH, Porter ML: Long-term results of cemented Charnley low-friction arthroplasty in patients aged less than 30 years. J Arthroplasty 13:123, 1998
13. Devitt A, O'Sullivan T, Quinlan WL: 16 to 25 year follow-up study of cemented arthroplasty of the hip in patients aged 50 years or younger. J Arthroplasty 12:479, 1997
14. Wroblewski BM, Fleming PA, Hall RM, Siney PD: Stem fixation in the Charnley low-friction arthroplasty in young patients using an intramedullary bone block. J Bone Joint Surg Br 80:273, 1998
15. Callaghan JJ, Forest EE, Olejniczak JP, et al: Charnley total hip arthroplasty in patients less than 50 years old. J Bone Joint Surg Am 80:704, 1998
16. Dorr LD, Kane TJ, Conaty JP: Long-term results of cemented total hip arthroplasty in patients 45 years old or younger. J Arthroplasty 9:453, 1994
17. Kay RM, Dorey FJ, Johnston-Jones K, et al: Long-term stability of cemented primary total hip arthroplasty. J Arthroplasty 10S:29, 1995
18. Shinar AA, Harris WH: Cemented total hip arthroplasty following previous femoral osteotomy: an average 16 year follow-up study. J Arthroplasty 13:243, 1998
19. Kaplan EL, Meier P: Nonparametric estimation from incomplete observations. J Am Statist Assoc 53:437, 1958
20. Dorey F, Amstutz HC: The validity of survivorship analysis in total joint arthroplasty. J Bone Joint Surg Am 71:544, 1989