Primary Total Hip Arthroplasty without the Use of Bone Cement: A 10-Year Follow-up of 157 Hips

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Background: The cementless fixation technique in total hip arthroplasty (THA) was developed to solve clinical problems such as aseptic loosening and osteolysis which were thought to be associated with the use of bone cement. This retrospective study reports our mid-term results with cementless THA.

Methods: A series of 173 consecutive, unselected cementless THA procedures using the Omnifit prosthesis was performed by a single surgeon. Sixteen hips were excluded from the study because of insufficient follow-up evaluation. One hundred and fifty-seven THAs with an average follow-up period of 10.2 (range, 5-12) years were retrospectively reviewed.

Results: The overall revision rate was 7.0%. Ninety-five percent of unrevised hips achieved a Merle D'Aubigne hip score of 16 points or above. Radiographically, bone ingrowth occurred in all unrevised cups, and in 95% of unrevised stems. Osteolytic lesions, seen on 28.1% of femora and 8.9% of pelvises, appeared at an average of 3.8 years postoperatively. Femoral osteolytic lesions were confined to the proximal Gruen zones 1 and 7. The mean annual polyethylene wear rate was 0.15 mm. Approximately 1/3 of the hips were noted to have excessive wear.

Conclusion: These results suggest that cementless Omnifit THA provides stable fixation for as long as 12 years after implantation. Of significant concern is the high incidence of excessive polyethylene wear and associated osteolysis. Our experience also indicates that a femoral stem with a circumferential porous coating in the proximal region can protect the femur from distal osteolysis.
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Key words: **total hip arthroplasty, cementless, osteolysis.**

Aseptic loosening and osteolysis are 2 major problems in long-term follow-up of cemented total hip arthroplasty.[1-5] They are especially of great concern in young and physically active patients.[5,6] There has been increased interest in the use of cementless fixation in order to solve these problems since the late 1970s. Short-term studies revealed that bone ingrowth occurs early.[7-10] It was anticipated that late component loosening due to cement aging could be avoided by the introduction of biologic fixation. However, bone loss secondary to osteolysis (previously called "cement disease") was not elimi-

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nated even with total hip arthroplasties that did not cement.[11,12] Furthermore, uncemented implants, especially the femoral components, have produced other concerns such as thigh pain, stress shielding, and the optimal extent of porous coating for adequate bone ingrowth.[13-16] The purpose of this study is to present clinical and roentgenological results of a single surgeon series using the cementless Omnifit total hip system (Osteonics, Allendale, NJ), with an average 10.2 years of follow-up.

METHODS

Between January 1989 and December 1990, we performed 173 primary total hip arthroplasties in 148 consecutive, non-selected patients using the Omnifit femoral and acetabular components. Follow-up periods ranged from 5 to 12 with an average of 10.2 years. Eleven patients (16 hips) were unable to complete the 5-year follow-up course (4 died, 7 were lost to follow-up). Thus the study group consisted of 157 hips in 137 patients. They were relative young patients with a mean age of 46.3 (range, 19-82) years. Details regarding the gender, age, diagnosis, body weight, and follow-up period of these patients are listed in Table 1.

Table 1. Demographic Data

Hips		157
Right		82
Left		75
Gender (M/F)		70/67
Mean age (years)		46.3
Diagnosis of hip pathology		
ON		78
OA		62
AS		7
RA		7
Others		3
Body weight (kg)	59.9 (range, 28-93)	
Follow-up (years)	10.2 (range, 5-12)	

Abbreviations: ON: osteonecrosis of the femoral head; OA: osteoarthritis; AS: ankylosing spondylitis; RA: rheumatoid arthritis.

The acetabular component of the Omnifit total hip system is designed as a hemispherical shell made of titanium alloy, with a surface preparation of a double layer of beads of between 425 and 500 um in size. All cups in this study had a 26-mm inner diameter polyethylene liner. The femoral component was manufactured from a cobalt chromium molybdenum alloy. It was collarless and straight, and the proximal 1/3 of the stem was circumferentially coated with 2 layers of cobalt chromium-sintered beads of 425 to 500 um in size.

All procedures were performed by a single surgeon (the senior author) using a posterolateral approach without the need of a trochanteric osteotomy. The proper-sized femoral and acetabular components were implanted after adequate reaming to achieve maximal metaphyseal canal filling and initial stability using the press-fit technique. When necessary, the acetabular component was supplemented with dome screws to provide further immediate stability. However, screw augmentation was not required in most cases, and a large proportion of the cups were implanted with a non-hole design.

Perioperative parenteral antibiotic therapy was administered for prophylaxis. Anticoagulants were not routinely used except in cases with high risk of deep vein thrombosis. Patients were mobilized after the surgery but remained partial weight-bearing with ambulatory aid for a period of 3 months.

All patients were regularly followed-up at intervals of 3 and 12 months, and annually thereafter. Clinical hip ratings were evaluated according to the scale described by Merle d'Aubigne and Postel for pain, walking ability, and range of motion with a maximal scale of 18 points (6 points for each item).[17]

Radiographic evaluation was performed by examining the anteroposterior and lateral radiographs taken preoperatively, immediate after the surgery, and at each follow-up visit. Revised hips were excluded from the radiographic and functional evaluations.

The acetabular component was considered unstable if there was definite migration or a change in position. Porous shedding or screw breakage was also suggestive of a loose cup. The stability of the femoral component was evaluated as described by Engh et al.,[7] and was divided into 3 categories: (1) stable bone ingrowth without radiolucent lines in the porous-coating area; (2) stable fibrous ingrowth if there were parallel sclerotic lines in the porous-coating area, but no definite subsidence or change in

implant position; and (3) unstable stem if there were divergent sclerotic lines around the prosthesis, or if it had progressively subsided or changed position. A pedestal setting at the tip of the stem and sclerosis of the calcar region were considered relatively unstable signs on the radiographs. In contrast, proximal femoral osteopenia, streaming trabeculations around the porous surface, and cancellous condensation at the distal extent of the coating ("spot welds") were indicative of bone ingrowth.

We defined osteolysis as any discrete area of endosteal scalloping greater than 2 mm in any direction, which was adjacent to the femoral or acetabular component on serial radiographs, but not on the immediate postoperative films. The distribution of osteolytic lesions on the pelvic sides were recorded according to the zonal system described by Delee and Charnley,[2] and on the femoral sides by Gruen et al.[4]

Linear polyethylene wear was measured using a computer-based system with a digitizer and special software of our own design. This method of measurement was published previously.[18] Excessive wear was defined as more than 0.2 mm of wear annually.

RESULTS

The clinical and radiographic results are listed in Table 2. At the latest follow-up, 5 hips had been revised for aseptic loosening (3 for femoral and 2 for acetabular components). One hip was revised because of deep infection. Another 5 revisions have been performed due to severe polyethylene wear, although there was no functional deterioration. The overall revision rate was 7.0% (11 of 157 hips). The revised hips were excluded from clinical and radiographic evaluations.

Among the remaining hips, the mean Merle d'Aubigne and Postel hip score was 16.9 points at the final evaluation (pain 5.8, walking ability 5.4, range of motion 5.7). Ninety-five percent of them reached a total score of 16 points or higher. The incidence of thigh pain was very low (1 hip).

There was no migration or circumferential radiolucent zone greater than 2 mm in the unrevised cups. Fixation status of the 146 surviving stems included bone ingrowth in 139 hips (95.2%) and stable fibrous ingrowth in 7 hips (4.8%). Femoral osteolysis was seen in 41 (28.1%) of unrevised hips. All of them were found on the proximal femora, in Gruen zones 1 and 7. Acetabular osteolysis was much less than its femoral counterpart and was observed in only 13 hips (8.9%). There were 6 hips with lesions in zone 1, 4 hips in zone 2, and 3 hips in both zones 1 and 2. Most of the osteolytic lesions were small with the largest diameter of less than 2 cm. Therefore, re-operations for curettage and bone grafting were undertaken in only 5 hips (3.4%).

Table 2. Clinical and Radiographic Results at 12 Years

Clinical Results		
No. of revisions	11/157 (7.0%)	
Loose cup		2
Loose stem		3
PE wear		5
Deep infection		1
Hip score	16.9	
Pain		5.8
Walking		5.4
ROM		5.7
Radiological results (unrevised hips)		
Stability		
Bone ingrowth		
Cup	146 (100%)	
Stem	139 (95.2%)	
Fibrous and stable ingrowth		
Cup	0	
Stem	7 (4.8%)	
Osteolysis		
Pelvis	13 (8.9%)	
Femur	41 (28.1%)	
Linear PE wear	0.15 mm/year	

Abbreviations: PEL: polyethylene; ROM: range of motion.

The mean linear wear rate of the polyethylene liner was 0.15 mm/year. It was quite constant with no effect of longevity of the prosthesis. Excessive wear was seen in approximately 1/3 of our cases (49/146)(Fig. 1).

There was no nerve palsy or deep vein thrombosis in this series. Deep infection was noted in 1 hip 3 years after implantation. It was treated with a 2-stage revision technique. Postoperative fractures of the greater trochanter occurred in 6 hips. Conservative treatment with the use of crutches for walking and restriction of activities was suggested for 4 fractures. The other 2 fractures had to be treated with open reduction and internal fixation because

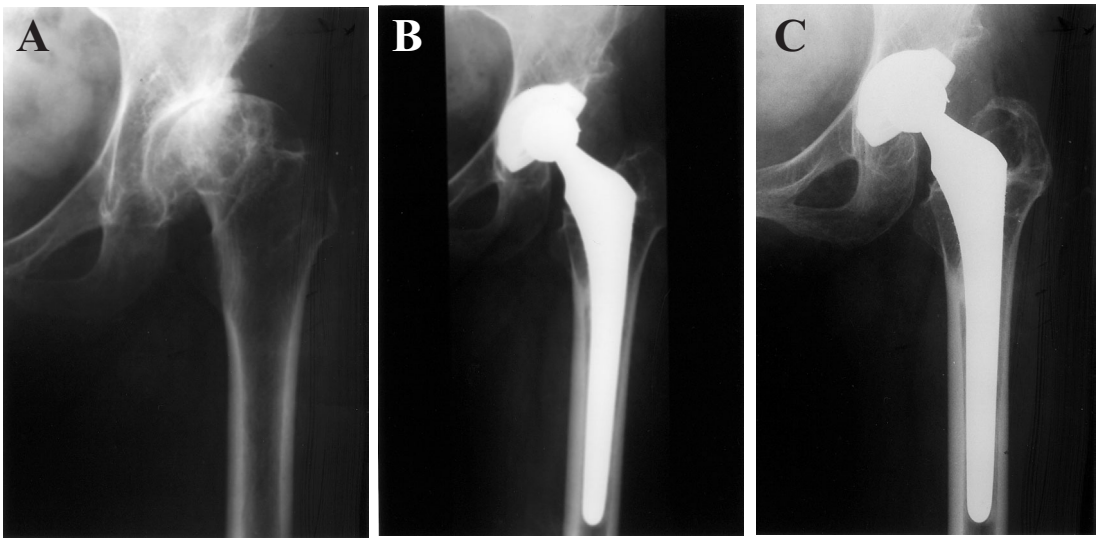

Fig. 1 (A) Anteroposterior radiograph showing the left hip of a 52-year-old female who had osteoarthritis secondary to hip dysplasia. (B) Five years after total hip arthroplasty, radiograph showing good implant stability although osteolysis is evident on the proximal femur. (C) Twelve years postoperatively, the prosthesis has remained stable with strong evidence of bone ingrowth. The osteolytic cyst has enlarged. There is eccentric polyethylene wear. The mean linear wear rate in this case is 2.4 mm/year.

of fracture displacement. They all healed well and regained their pre-fracture function. Eleven patients were rehospitalized for traction after closed reduction for postoperative dislocation. Heterotopic ossification was seen in 6 hips. None of these patients required a reoperation.

DISCUSSION

Although total hip arthroplasty is now one of the most commonly performed reconstructive procedures in orthopedic surgery, controversy remains concerning the best method of fixation to maintain a durable, ageless interface between the prosthesis and the host.[19] The use of acrylic cement has the advantage of obtaining immediate stability. However, the good results with cemented implants can deteriorate with time, especially in younger, more-active patients.[5,6] Cementless porous-coated prostheses were later introduced as a potential solution to the problem with their ability to achieve direct biologic fixation by means of bone ingrowth.

Despite numerous published reports regarding cementless total hip replacement,[8-10,13,20,21] long-term results are still lacking in the literature. In this series of 157 hips with an average 10.2 years of follow-up, we report a 3.2% overall incidence of aseptic loosening which is quite low compared to those of most previous short-term and mid-term studies. We also note high rates of bone ingrowth into the prosthesis, both in the femoral and acetabular components. These findings made us confident of durable implant stability even for longer follow-up periods. We attribute these good results to careful surgical techniques with the primary goal of achieving a press fit and maximal canal filling, as advocated by Engh et al.[22] Our findings also confirm that femoral stems with a porous-coating surface only on the proximal 1/3 are adequate for stable fixation.

Patients in this study group demonstrated satisfactory clinical scores. The incidence of thigh pain was very low (< 1%). This is quite different from some previous studies using other designs of cementless femoral components. Dodge et al., Engh et al., Kim and Kim, McAuley et al., and Petersilge et al. reported high rates of thigh pain even with a stable prosthesis (8%-40%).[20,21,23-25] On the other hand, Hellman et al. and Mclaughlin and Lee stated that thigh pain is a rare clinical occurrence.[26,27] Our finding is consistent with their observations. Thigh pain

in this study group was too rare to be a clinical problem. Although conflicting results exist, the true etiology of thigh pain is still uncertain.

Osteolysis has been an area of great concern in total hip arthroplasty in recent years. Current concepts suggest that polyethylene wear debris plays a major role in inducing the process of bone destruction.[3,11,12] In the present series, osteolytic lesions were seen much less on the pelvic than those on the femoral counterpart (8.9% vs. 28.1%). In a short-term study of Omnifit cementless implants, Chen et al. reported a 38.01% incidence of femoral osteolysis compared to only 9.68% for pelvic lesions.[28] Hellman et al. evaluating the same prostheses at 10 years also reported a tendency of much greater osteolysis on the femur (35.7%) than on the pelvis (4.3%).[26] While both demonstrated similar results, the possible reason for this difference was not discussed in their studies. In this series, a large proportion of cup components were implanted using a design with no screw holes. This may, at least in part, explain the low incidence of osteolysis seen on the pelvis since the particulate debris could gain no access to the periprosthetic host bone.

Femoral osteolytic lesions in our series were all confined to the proximal Gruen zones 1 and 7. There was no incidence of distal femoral endosteal erosion. This finding suggests that bone ingrowth or fibrous integration around the proximally and circumferentially coated femoral components can protect against distal osteolysis. This is also supported by other previous reports using the anatomic medullary locking (AML; Depuy, Warsaw, IN) and Multilock (Zimmer, Warsaw, IN) stems. The designs of the femoral components of both prostheses are similar. Engh et al. and Maloney et al. used these types of prostheses and reported a similar distribution of femoral osteolysis.[23,29]

On the contrary, the Harris-Galante (Zimmer, Warsaw, IN) and anatomic porous replacement (APR-I; Intermedics, Austin, TX) stems have a patched proximal porous coating. The smooth seams between the porous areas provide pathways for access of debris to the distal portions of the interface. The particles then stimulate a scalloped pattern of endosteal bone loss in the smooth diaphysis. Studies on such prosthesis designs revealed that the incidence of osteolysis ranged from 8% to 52%.[12,30-32] But they uniformly demonstrated osteolytic lesions to be located in the diaphyseal portions, predominantly in Gruen zones 3, 4, and 5.

The time of appearance of osteolysis varied from 2 to 9 years postoperatively, with an average of 3.8 years. Most osteolytic lesions found in our patients were too small to be clinically significant. Thus, reoperations for curettage and bone grafting had to be performed in only 5 patients in the 10.2-year follow-up. However, since wear processes continue and untreated cysts remain accessible to the polyethylene debris, progression of osteolysis is expected in later follow-up. Additional bone grafting procedures will be required before implant stability is threatened.

To reduce wear debris of polyethylene liners and the resultant osteolysis, cross-linking is currently used in an attempt to improve the wear performance of polyethylene in the hip joint replacement. Cross-linking converts the polyethylene molecules into an interpenetrating, networking structure of polymer chains. Laboratory hip simulator wear tests have shown that there is a decrease in wear rate with an increase in degree of cross-linking of polyethylene.[33]

Some authors avoid the use of polyethylene articulation with the hope that osteolysis can be reduced. The most-common alternative approaches are the metal-on-metal and the ceramic-on-ceramic wear pairs. The metal-on-metal system clearly produces a much smaller amount of wear debris than does the conventional poly-metal system with a linear wear rate of 2.5 to 5 μm/year.[34] The ceramic-on-ceramic bearing shows an even lower wear rate than the metal-on-metal, perhaps as low as 0.5 to 2.5 μm/year.[35] There are, however, no data available so far regarding long-term, prospective comparisons of these different bearing surfaces and their associated rates of osteolysis.

Our senior author reported a method of measuring polyethylene wear using a digitizer and special software.[18] The present series is a major subgroup of that previous study. We have shown that linear wear rates correlate well with age and with osteolysis, but not with other clinical parameters such as weight, gender, diagnosis, thickness of polyethylene liner, and the position of cups.[18]

In conclusion, this midterm study demonstrates that cementless total hip arthroplasty with an Omnifit prosthesis is a feasible procedure to achieve satisfactory pain relief, good functional results, and durable

implant stability with a low rate of complications at 5 to 12 years. However, a relatively high incidence of polyethylene wear and osteolysis should be taken into serious consideration. Further studies are obviously necessary to assess long-term outcomes.

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無骨水泥人工髖關節置換：157例平均10年之追蹤報告

謝邦鑫　施俊雄[1]　李柏成　陳志華　楊文一

背 景： 無骨水泥固定之人工髖關節置換術乃是發展用以解決無菌性鬆動及骨溶解現象等被認爲因骨水泥而引起之併發症。本文將報告我們中期的經驗。

方 法： 收集173件連續的、未經選擇的，且由同一位醫師以Omnifit廠牌之產品實行的無骨水泥全人工髖關節置換的案例。其中16個案例因追蹤不足而不列入。因此，樣本數爲157個案例，平均追蹤達10.2年(範圍5至12年)。

結 果： 需再置換比率爲7.0%。未經再置換者中有93%可達Merle D'Aubigne hip score 16分以上。放射學追蹤則可發現所有髖臼杯及95.2%的股骨柄可見骨長入之証據。骨溶解現象平均出現於術後3.8年。28.1%的股骨及8.9%的骨盆可見此一現象。所有股骨的骨溶解現象皆發生於近端的Gruen第一及第七區。聚乙烯之年平均磨耗爲0.15mm。大約有三分之一的案例有過度磨耗的現象。

結 論： 本文之結果顯示Omnifit無骨水泥固定之全人工髖關節置換可提供足夠之穩定度達至少12年之久。然而，值得特別關注的問題是聚乙烯過度磨耗及伴隨而來之骨溶解現象。我們的經驗同時也指出了近端有環狀孔洞披覆設計的股骨柄能有效使得遠端股骨免於發生骨溶解現象。

(長庚醫誌 2002;25:298-305)

關鍵字： 全人工髖關節置換，無骨水泥，骨溶解現象。

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