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Femoral Head Size of 36 mm against Highly Cross-linked Polyethylene in Patients Younger than 60 Years: Minimun Three Years of Follow Up

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Purpose: The purpose of this study was to evaluate the early results of total hip arthroplasty (THA) performed using large diameter femoral head against with highly cross-linked polyethylene as a bearing surface in patients less than sixty years of age.

Materials and Methods: Seventy patients were enrolled and retrospectively reviewed. The mean age of patients at index surgery was 49 years and the mean follow-up period was 61 months. Clinical follow-up involved implementing the Harris hip score (HHS) and a radiographic evaluation that included linear radiolucency, osteolysis, and loosening. An annual wear rate was performed at 6 weeks; at 3, 6, and 12 months; and on a yearly basis thereafter.

Results: The average HHS at last follow-up was 94 (range: 82-98). Radiographically, no osteolysis in the pelvis or proximal femur was observed in any patient. No acetabular cup or femoral stem failed due to aseptic loosening. No eccentric wear was observed on any liner, and no liner fracture occurred. However, one patient experienced hip dislocation. The average femoral head penetration rate during the first postoperative year was 0.077±0.026 mm/year, and the average steady-state wear rate was 0.033±0.023 mm/year.

Conclusion: THA with a large diameter femoral head of highly cross-linked polyethylene in patients younger than 60 years of age was found to produce results comparable to previous in vitro laboratory hip simulation studies. In particular, patient satisfaction was high due to no limitation in range of motion or hip posture during the early post-operative period. Longer-term follow-up is required to demonstrate the clinical benefits of this new material more comprehensively.

Key words: total hip arthroplasty, large femoral head, highly cross-linke polyethylene, less than 60 years old

INTRODUCTION

Particulate wear debris after total hip arthroplasty (THA) conducted using conventional ultra-high-molecular-weight polyethylene (UHMWPE) is closely related to periprosthetic osteolysis and aseptic component loosening. Large diameter femoral heads provide a means of reducing the risk of dislocation, but increases in wear debris have prevented the widespread use of this option in primary articulation.[1-5] In general, younger patients have higher activity levels, and thus, show higher levels of polyethylene wear.[6] Furthermore, implants placed in younger patients must also have greater longevity. Potential concerns regarding the use of highly cross-linked polyethylene include a reduction in yield and ultimate tensile strengths due to the embrittling effects of the radiation used for cross-linking.[7] Even though case reports of early failure implicated impingement,[8] this known reduction in material properties might imply a theoretical risk in young patients.[9] Nevertheless, early and intermediate-term results of THA using highly cross-linked polyethylene bearing surfaces are promising.[1,10,11] Base on these findings, we hypothesized that THA conducted using a 36 mm femoral head paired with highly cross-linked polyethylene would show low rates of dislocation and no appreciable wear debris. However, it is unclear whether these lower wear rates are achieved in younger patients, because of a paucity of clinical data regarding the performance of THA using large diameter femoral heads on highly cross-linked

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polyethylene in this population. Accordingly, the purpose of this study was to evaluate the early clinical and radiographic results (at a minimum follow-up of three years) of THA using a large diameter femoral head on highly cross-linked polyethylene in patients less than sixty years old.

MATERIALS AND METHODS

Our institutional ethics committee reviewed and approved the study protocol, and all patients provide written informed consent before undergoing screening procedures on April 2010. We retrospectively reviewed 70 patients (70 hips) that underwent THA with a large diameter femoral head on highly cross-linked polyethylene between August 2004 and March 2007 (Table 1). The mean age of index surgery was 49 years (range: 28-59 years, 34 males and 36 females) and mean follow-up was 61 months (range: 36-78 months). A cementless metal shell with a porous coating (Trilogy®, Zimmer Inc., Warsaw, IN, USA) and a highly cross-linked polyethylene liner with an inner diameter of 36 mm (Longevity®, Zimmer Inc.) was placed in all patients. Based on surgeon's preference, one or two screw augmentations were adopted. Acetabular components had a mean outer diameter of 54 mm (range: 50-62 mm). The polyethylene liners were machined from GUR 1020 (Warsaw, IN, USA) 1,050 polyethylene, which had been pre-heated and cross-linked with a 9.5 Mrad electron-beam. The preforms were then melted to eliminate the remaining free radicals and steriltzed using a gas plasma. FMT (Zimmer Inc.) components were used in 64 patients who underwent uncemented femoral fixation and Versys (Zimmer Inc.) components in 6 patients who underwent cemented femoral fixation. All cementless stems were inserted using standard press fit techniques to insure longitudinal and rotational stability, and all cemented femoral stems were inserted using meticulous third generation cementing techniques. All surgical procedures were performed by one surgeon using a modified Hardinge approach with the patient in the lateral position. Sixty patients underwent capsular repair closure. Prophylactic antibiotics were administrated to all patients, and the same post-operative protocol was used in all. Patients were allowed to sit on the first post-operative day and stand with support, according to ability, after blood drainage removal. No range of motion (ROM) limitation was present immediately after surgery, and no abduction pillow was used in any patient. Patients were followed at 6 weeks, and at 3, 6, and 12 months and every year thereafter postoperatively. The clinical and radiographic evaluation was performed by an independent surgeon who did not participate in THA. Clinical follow-ups included specific assessments of possible dislocation, in addition, Harris hip score (HHS)[12] was determined. HHS was classified as excellent (91-100), good (81-90), fair (71-80), or poor (61-70). In cases that underwent uncemented fixation, the status of fixation of femoral component was assessed using Engh et al[5]'s method, and in cases that underwent cemented fixation, femoral components were assessed the amount of cement filling using Barrack et al[6]'s method using immediate postoperative radiographs. The six-week pelvis centered over the pubis and cross-table lateral radiographs were considered to be the baseline studies for radiographic comparison. The final radiographic evaluation included an assessment of the fixation of the acetabular and femoral components, progression of radiolucency, wear, osteolysis and heterotopic ossification. Abduction and anteversion angles of the acetabular components and alignments of the femoral stems were measured on six-week anteroposterior radiographs. The abduction angle of the acetabular component was measured using the method described by Engh et al[13] and Kennedy et al.[14] The anteversion of the acetabular component was calculated using the method of Widmer[15] and it also calculated using polyWare pro 3D distal version 5.10 software (Draftware Developers Inc., Vevay, IN, USA). Osteolytic lesions were defined according to the criteria of Engh et al.[16] The lesions were recorded according to the three zones described by DeLee and Charnley[17] on the acetabular side and the seven zones described by Gruen et al[18] on the femoral side. Heterotopic ossification was classified according to the system of Brooker et al.[19] Penetrations of femoral heads into polyethylene liners were calculated as two-dimensional linear penetrations on anteroposterior radiographs of the pelvis using polyWare pro 3D distal version 5.10 software (Draftware Developers Inc.). The mean total femoral head penetration was calculated by determining the magnitude of femoral head penetration shown 1st postoperative and final follow-up radiographs, and normalizing with respect to the duration of radiographic follow-up. The total penetration rate of

Table 1. Number of Patients and Diagnosis

Diagnosis	Number (patients)
Osteonerosis	26
Osteoarthritis	26
Rheumatoid arthritis	8
Femoral neck fracture	7
Ankylosing spondylitis	2
Pathologic neck fracture	1
Total	70

the femoral head into the acetabular polyethylene is a result of the plastic creep and wear of the liner. To separate the early bedding-in process from steady-state wear, we calculated steady-state wear rate between 1-year postoperative plain radiographs and final follow-up plain radiographs.

RESULTS

Average modified HHS at final follow-up was 94±10.4 (range: 82-98), and it was better than 'good' in all cases. Radiographic final follow-up exams showed stable fixation in all patients with uncemented femoral components, and Barrack type A or B in all patients with cemented femoral components. Mean acetabular shell abduction and anteversion were 43° (range: 29-53°) and 22° (range: 5-38°), respectively. There was no radiographic evidence of osteolysis in the pelvis or proximal femur, and no acetabular cup or femoral stem failed due to aseptic loosening. Furthermore, there was no evidence of cup migration, screw breakage, eccentric liner wear, or liner fracture. One patient developed a hip dislocation (Table 2). This patient had osteonecrosis of the femoral head and hip joint arthritis, which developed at 18 months after fixation of an acetabular fracture. In this patient, anteversion of the index cup was 5°. She dislocated at 4 weeks and at 18 months after THA. The patient underwent isolated acetabular revision at second dislocation, and has done well since. In all patients, average femoral head penetration during the first postoperative year (predominantly representing polyethylene creep) was 0.077±0.026 mm/year, and the average steady-state wear rate was calculated using 1-year postoperative radiographs and the latest

Table 2. Summary of Clinical and Radiographic Outcomes

Parameter	Values
Harris hip score	94±10.4 (range: 82-98)
Merle d'Aubigne and Postel score	15 (range: 15-18)
Complication	
Osteolysis	0
Loosening	0
Infection	0
Periprosthetic fracture	0
Polyethylene liner fracture	0
Dislocation	1
Femoral head penetration during bedding-in time	0.077±0.026 mm/year
Average steady-state wear rate	0.033±0.023 mm/year

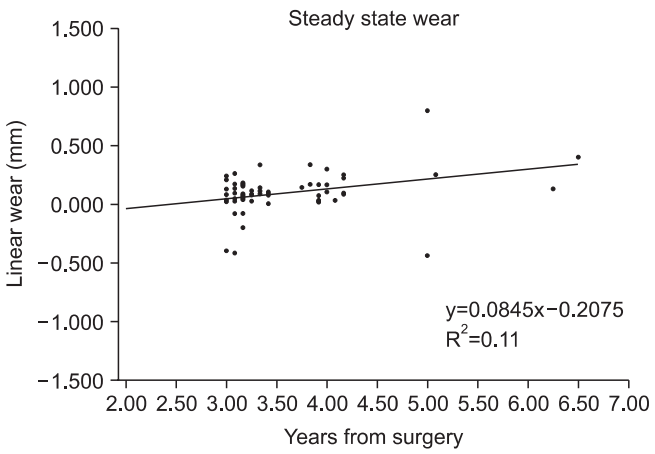

Figure 2. A scatter plot of the femoral head penetration measured between the first-year postoperative radiographs and acceptable follow-up radiographs. The steady-state wear rate is represented by the slope of the best fit linear regression line.

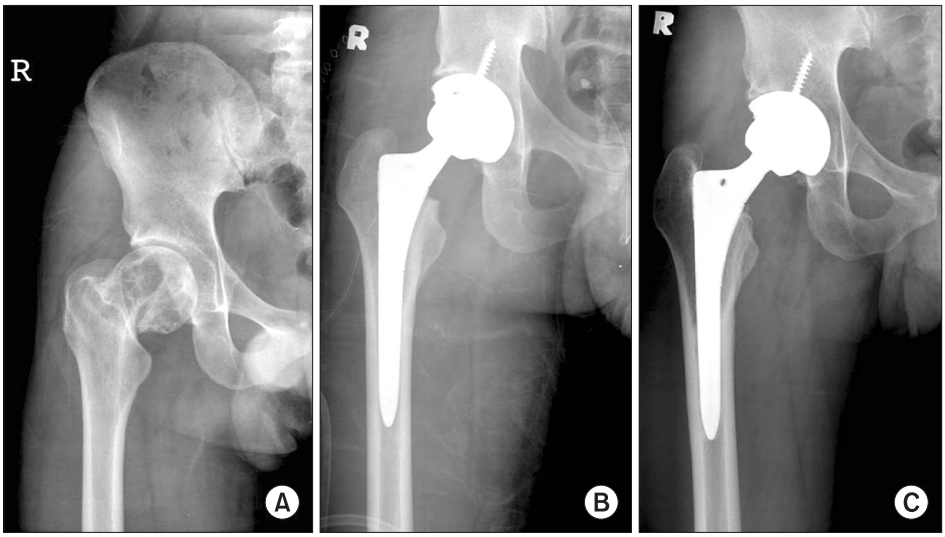

Figure 1. Plain pelvis anterior-posterior radiograph of a 21-year-old man showed femoral neck fracture with the chondroblastoma (A). Total hip arthroplasty performed using a 36 mm femoral head in right hip (B). At 49 months postoperatively, Harris hip socpre was 98 point and steady-state wear rate was 0.021 mm/year (C).

follow-up, and it was 0.033±0.023 mm/year (Fig. 1, 2).

DISCUSSION

Larger diameter femoral heads are believed to be less prone to dislocation and facilitate higher ROMs.[2,3,20-24] However, the widespread adoption of larger diameter femoral heads against conventional polyethylene is limited by the risk of accelerated wear and resulting osteolysis.[2,15] The development of a new cross-linked polyethylene with improved wear characteristics, according to early laboratory and clinical studies, could reduce the risk of wear. Hip simulator studies have also demonstrated very low wear rates for even larger heads when a highly cross-linked polyethylene liners are used.[2,4] Especially, accelerated rates of polyethylene wear and the increased prevalence of osteolysis are particularly important problems in young, more active patients,[6] and previous studies have reported that a direct relationship exists between the amount of wear and the rate of periprosthetic osteolysis. Polyethylene wear rates of less than 0.1 mm per annum have been associated with freedom from osteolysis, whereas rates exceeding 0.3 mm per annum have been reported to result in inevitable osteolysis.[25] Therefore, alternative bearing surfaces have been introduced to minimize wear particle-induced implant failure. In particular, highly cross-linked polyethylene was introduced for use in THA to reduce periprosthetic osteolysis secondary to a reduction in wear debris.[26] This electron beam-irradiated highly cross-linked polyethylene has been extensively studied, and shown to have substantially improved wear characteristics in vitro. Furthermore, these reductions in wear appeared have been reported to be independent of head size.[2,4,27]

In the present study, even though one patient experienced a hip dislocation, patient satisfaction was high due to no ROM or hip posture limitation during the early post-operative period. However, despite the stability advantage observed during this study, the occurrence of this dislocation indicates the importance of proper orientation of the acetabular and femoral components during surgery.[28] Some obstacles exist regarding the use of a large diameter femoral head on highly cross-linked polyethylene. Polyethylene thickness is considered an important wear rate factor, a patient must have a 50 mm diameter acetabulum to allow a 36 mm femoral head to be used. Even though insuring adequate polyethylene thickness may or may not be an issue with highly cross-linked polyethylene, this evidence concerns the increased wear rates of thin UHWPE liners.[20-22] In the present study, acetabular components had a mean outer diameter of 54 mm (range: 50-62 mm), and thus, need careful observation for polyethylene wear because liners were less than 6 mm thick. Even though edge fractures (3 cases among 150,000) of highly cross-linked polyethylene liners were attributed in one study to component malpositioning, it might still be an important issue.[4,8]

The possibility of fatigue failure due to decreases in yield strength and ultimate tensile strength caused by the cross-linking process emphasizes the need for long-term in vivo studies in young active patients. The early bedding-in of the femoral head resulting from plastic creep and other factors can confound early measurements of wear. Estok et al[29] reported a femoral head penetration resulting from creep of ~0.1 mm for both conventional and highly cross-linked polyethylene. In the present study, the magnitude of femoral head penetration during the first postoperative year was 0.077±0.026 mm/year. We found that the early annual wear rate (0.033±0.023 mm/year) of cross-linked polyethylene in patients less than 60 years was lower than for conventional polyethylene, and comparable to published data for older populations. Minor differences between our values for wear rate and published values are probably due to measurement errors associated with measurement techniques. This is reflected in the fact that the wear rate observed in the present study is similar to the standard deviation. However, it should be noted that the present study has limited statistical power because the cohort was not prospectively randomized and the follow-up was relatively short. Nonetheless, the early result of THA with a large diameter femoral head on highly cross-linked polyethylene in patients less than 60 years was found to be comparable with in vitro laboratory hip simulation studies, and was found to be associated with high patient satisfaction due to no ROM or hip posture limitations during the early post-operative period. However, further follow-up studies are required to evaluate long-term wear-rates and the development of osteolysis.

CONCLUSION

THA with a large diameter femoral head on highly cross-linked polyethylene in patients less than sixty years of age was found to produce the results comparable to previous in vitro laboratory hip simulation studies. In particular, patient satisfaction was high due to no ROM or hip posture limitation during the early post-operative period. Longer-term follow-up is required to demonstrate the clinical benefits of this new material more comprehensively.

REFERENCES

1. Burroughs BR, Rubash HE, Harris WH. Femoral head sizes larger than 32 mm against highly cross-linked polyethylene. Clin Orthop Relat Res. 2002;(405):150-7.
2. Geller JA, Malchau H, Bragdon C, Greene M, Harris WH, Freiberg AA. Large diameter femoral heads on highly cross-linked polyethylene: minimum 3-year results. Clin Orthop Relat Res. 2006;447:53-9.
3. Harris WH. Highly cross-linked, electron-beam-irradiated, melted polyethylene: some pros. Clin Orthop Relat Res. 2004;(429):63-7.
4. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J Bone Joint Surg Am. 1969;51:737-55.
5. Engh CA, Bobyn JD, Glassman AH. Porous-coated hip replacement. The factors governing bone ingrowth, stress shielding, and clinical results. J Bone Joint Surg Br. 1987;69:45-55.
6. Barrack RL, Mulroy RD Jr, Harris WH. Improved cementing techniques and femoral component loosening in young patients with hip arthroplasty. A 12-year radiographic review. J Bone Joint Surg Br. 1992;74:385-9.
7. Hammerberg EM, Wan Z, Dastane M, Dorr LD. Wear and range of motion of different femoral head sizes. J Arthroplasty. 2010;25:839-43.
8. D'Antonio JA, Manley MT, Capello WN, et al. Five-year experience with Crossfire highly cross-linked polyethylene. Clin Orthop Relat Res. 2005;441:143-50.
9. Martell JM, Verner JJ, Incavo SJ. Clinical performance of a highly cross-linked polyethylene at two years in total hip arthroplasty: a randomized prospective trial. J Arthroplasty. 2003;18(7 Suppl 1):55-9.
10. Cho MR, Lee JK, Lee HS. Comparison of bipolar hemiarthroplasty and total hip arthroplasty using large heads in patients with femoral neck fractures. J Korean Orthop Assoc. 2009;44:514-9.
11. Cho MR, Kim SS, Lee HS. Total hip arthroplasty using a large femoral head: the short-term follow-up results and the early complications. J Korean Hip Soc. 2009;21:232-7.
12. Cho MR, Lee HS. Early results after the treatment with total hip arthroplasty with larger diameter femoral head versus bipolar arthroplasty in patients with femoral neck fractures. J Korean Hip Soc. 2007;19:463-7.
13. Engh CA, Griffin WL, Marx CL. Cementless acetabular components. J Bone Joint Surg Br. 1990;72:53-9.
14. Kennedy JG, Rogers WB, Soffe KE, Sullivan RJ, Griffen DG, Sheehan LJ. Effect of acetabular component orientation on recurrent dislocation, pelvic osteolysis, polyethylene wear, and component migration. J Arthroplasty. 1998;13:530-4.
15. Widmer KH. A simplified method to determine acetabular cup anteversion from plain radiographs. J Arthroplasty. 2004;19:387-90.
16. Engh CA, Hooten JP Jr, Zettl-Schaffer KF, Ghaffarpour M, McGovern TF, Bobyn JD. Porous-coated total hip replacement. Clin Orthop Relat Res. 1994;(298):89-96.
17. DeLee JG, Charnley J. Radiological demarcation of cemented sockets in total hip replacement. Clin Orthop Relat Res. 1976;(121):20-32.
18. Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. Clin Orthop Relat Res. 1979;(141):17-27.
19. Brooker AF, Bowerman JW, Robinson RA, Riley LH Jr. Ectopic ossification following total hip replacement. Incidence and a method of classification. J Bone Joint Surg Am. 1973;55:1629-32.
20. Bradford L, Kurland R, Sankaran M, Kim H, Pruitt LA, Ries MD. Early failure due to osteolysis associated with contemporary highly cross-linked ultra-high molecular weight polyethylene. A case report. J Bone Joint Surg Am. 2004;86-A:1051-6.
21. Heisel C, Silva M, dela Rosa MA, Schmalzried TP. Short-term in vivo wear of cross-linked polyethylene. J Bone Joint Surg Am. 2004;86:748-51.
22. Dowd JE, Sychterz CJ, Young AM, Engh CA. Characterization of long-term femoral-head-penetration rates. Association with and prediction of osteolysis. J Bone Joint Surg Am. 2000;82:1102-7.
23. Schmalzried TP, Szuszczewicz ES, Northfield MR, et al. Quantitative assessment of walking activity after total hip or knee replacement. J Bone Joint Surg Am. 1998;80:54-9.
24. McKellop H, Shen FW, Lu B, Campbell P, Salovey R. Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements. J Orthop Res. 1999;17:157-67.
25. Furmanski J, Anderson M, Bal S, et al. Clinical fracture of cross-linked UHMWPE acetabular liners. Biomaterials. 2009;30:5572-82.

26. Lachiewicz PF, Heckman DS, Soileau ES, Mangla J, Martell JM. Femoral head size and wear of highly cross-linked polyethylene at 5 to 8 years. Clin Orthop Relat Res. 2009;467:3290-6.
27. McCalden RW, MacDonald SJ, Rorabeck CH, Bourne RB, Chess DG, Charron KD. Wear rate of highly cross-linked polyethylene in total hip arthroplasty. A randomized controlled trial. J Bone Joint Surg Am. 2009;91:773-82.
28. d'aubigne RM, Postel M. Functional results of hip arthroplasty with acrylic prosthesis. J Bone Joint Surg Am. 1954;36:451-75.
29. Estok DM 2nd, Bragdon CR, Plank GR, Huang A, Muratoglu OK, Harris WH. The measurement of creep in ultrahigh molecular weight polyethylene: a comparison of conventional versus highly cross-linked polyethylene. J Arthroplasty. 2005;20:239-43.

60세 이하 환자에서 큰 대퇴 골두-플라스틱 관절면을 이용한 고관절 전 치환술: 최소 3년 추시 결과

박창민 • 조명래 • 김신근 • 추원권 • 권재범

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목적: 60세 이하의 환자에서 큰 대퇴 금속 골두-플라스틱 관절면을 사용한 인공 고관절 전 치환술의 초기 추시 결과를 연구하였다.

대상 및 방법: 후향성 연구로 70명을 연구하였고 평균 연령은 49세, 추시 기간은 61개월이었다. 수술 후 6주, 3개월, 6개월, 1년 및 1년 이후 매 1년마다 Harris hip score (HHS)를 이용하여 임상적 기능을 평가하였고 또한 삽입물의 이완, 골융해, 마모에 대하여 방사선학적으로 평가하였다.

결과: 최종 추시에서 HHS는 94점(범위: 82-98점)이었다. 방사선학상 근위 대퇴부와 골반부에 골융해, 비구부품과 대퇴 주대의 실패, 변연부 마모, 플라스틱 골절 등은 없었다. 한 예에서 탈구가 발생하였다. 평균 마모율은 첫 해에서는 0.077±0.026 mm/year였고, 이후는 0.033±0.023 mm/year였다.

결론: 60세 이하의 환자에서 큰 대퇴 금속 골두-플라스틱 관절면을 사용한 인공 고관절 전 치환술은 과거의 실험실의 연구와 비교할 만한 결과를 보였다. 특히 수술 후 환자의 고관절 운동과 자세에 제한을 두지 않아 환자 만족도가 높았다. 그러나 장기 추시가 연구의 임상적인 장점을 위해 필요할 것으로 판단된다.

색인단어: 고관절 전 치환술, 큰 대퇴 골두, highly cross-linked polyethylene, 60세 이하

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