Five Year Results of Hydroxyapatite Coated Hip System - Early Severe Wear and Acetabular Osteolysis -

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Purpose: To assess the midterm results of the hydroxyapatite hip system with acetabular cups, with particular emphasis upon cup wear and loosening, using a computer assisted-3 dimensional technique.

Materials and Methods: From March 1992 to December 1996, 52 patients (61 hips) were available for inclusion in this study after an average duration of follow up of 6 years and 4 months. Clinical evaluation was performed using the Harris hip scoring system. Initial postoperative and long term follow up films were digitized, and 2 dimensional linear and 3 dimensional wear was measured by using a computer assisted-3 dimensional technique. Acetabular bone changes are described using previous published methods.

Results: An analysis of the clinical results showed a mean Harris hip score of 47.2 points preoperatively and 89.8 points at the final visit. The mean polyethylene 3D-linear wear rate was 0.26 mm/year and mean volumetric wear rate was 105.9 mm³/year. In 16 hips (26.2%) the linear wear rate was more than 0.3 mm/year (0.30-0.74 mm/year). Osteolytic changes of the acetabulum were recorded in 51% around acetabular cups, in which considerable wear of the acetabular polyethylene was evident by the five-year radiographic findings.

Conclusion: Midterm results of hydroxyapatite coated acetabular cups were disappointing in terms of acetabular cup and liner wear, despite early accelerated bone remodeling by hydroxyapatite and excellent early clinical results.

Key Words: Total hip arthroplasty, Hydroxyapatite

In response to the failure to achieve reproducible bone ingrowth or clinical ingrowth with porous-coated implants, material specialists have developed ways of attaching osteoconductive coatings, such as hydroxyapatite (HA), to porous coated and press-fit implants, to assure skeletal attachment in active patients. Researchers have suggested that HA coatings could induce reproducible bone ingrowth and improve bone attachment as compared with porous-coated devices[1223].

HA coatings seem to provide improvements in the early histological and radiological results of the femoral side, according to reports, and clinical outcomes have been excellent, but radiographic results have pointed mainly to proximal femoral stress transfer. However, less concern has been expressed about the wear and loosening of acetabular cups, and the majority of studies measured 2 dimensional wear by simple roentgenography. Therefore, we undertook to assess the long-term results of HA coating these acetabular cups, using a more accurate computer assisted-3 dimensional technique.

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MATERIALS AND METHODS

From March 1992 to December 1996, 86 ABG (Anatomique Benoist Giraud, Howmedica Europe, Staines, England) primary total hip prostheses were implanted in 71 patients in two hospitals by two surgeons. Five patients (7 hips) died and fourteen patients (18 hips) was lost before minimum five-year follow up, leaving 61 hips (52 patients) available for inclusion in this study with an average follow-up of 6 years and 4 months. One periprosthetic fracture had healed after a long stem revision, bone graft and wiring. Two revisions showed excessive wear and acetabular cup loosening.

Of the fifty-two patients studied, forty-four were men and eight were women. At the time of hip replacement, their average age was 47.5 years (range, 21 to 65 years) and their average weight was 63.2 kilograms (range, 45 to 84 kilograms), and 82% of the 52 patients had a preoperative diagnosis of avascular necrosis of the femoral head (Table 1).

The ABG hip prosthesis was used in all hips (Fig. 1). The stem was made of titanium alloy (TA6V), and the hemispherical metal cups with 12 uniform screw-holes were made of the same alloy, and were totally coated with hydroxyapatite. 11 cup sizes are available (ranged from 42 to 62 mm). The femoral heads were made of cobalt-chromium and zirconia, and 28 mm in diameter. The hydroxyapatite coating of the implant had the following charac-
teristics: a chemical purity of more than 99.99%, and crystallo-
graphic composition of 98% to 99% hydroxyapatite with a max-
imum porosity of 2%. The very high mechanical resistance ranged
from 62 MPa to 65 MPa, and the coating thickness was 60 microns
(±10).

The surgical approach was posterolateral. Cup fixation was
achieved either with 1 or 2 spikes in 73.8% of patients, screws
only in 9.8%, or screws and spikes in 16.4%. Acetabular auto-
grafts were necessary in 6.6% of patients, whenever it was neces-
sary to build up a dysplastic acetabulum. 28 mm femoral head
sizes were used and made of cobalt-chromium in all patients. The
standard surgical procedure involved distal femoral overreaming
with flexible reamers. Right and left stems were available to accom-
modate the proximal anatomic press fit design.

Each patient was evaluated preoperatively, at 3, 6, and 12 mo-
ths, and annually thereafter, but in this study only the imme-
diate postoperative and last visit evaluation were used. Standard-
ized anteroposterior radiographs with the beam centered on the
symphysis pubis and lateral radiographs of the hip were taken at
each follow-up visit. The sizes of the acetabular components im-
planted were obtained from medical records. The thickness of
the polyethylene in each cup was calculated from the specifi-
cations provided by the manufacturer. As the polyethylene liner in
the acetabular components inserted without cement was thinner
at the rim than at the pole, because of the hexagonal locking me-
chanism, we calculated the thickness of the liner at the pole. Polyethy-
lene wear was measured using the three dimensional technique
described by Devane et al.10. Initial postoperative and the most
recent follow-up radiographs were digitized, and used by custom
software to produce a three-dimensional model of the prosthesis
from which measurements were taken. These measurements in-
cluded the orientation of the acetabular component (tilt and antev-
erision), two-dimensional linear wear, the three-dimensional dis-
tance and the direction of the displacement of the femoral head,
minimum volume of the polyethylene debris, and the displace-
ment of the femoral head with reference to the cup as viewed in
the frontal plane. Two-dimensional linear wear was measured in
the plane of the anteroposterior radiograph.

The cup position was assessed according to the criteria of Yodar
et al.23 and Masson et al.16. Cup angle was defined as the lateral
opening of the cup; cup height as the vertical distance between
the hip rotation center and the horizontal line connecting the 2
teardrops (inter-teardrop line); and the cup medialization distance
was measured with respect to a vertical line drawn to the inter-
teardrop line, as described by Masson et al.16. In cases in which
the teardrop was poorly visualized, the cup medialization distance
was measured in relation to Kohler’s line. Radioluencies around
the cup were assessed according to the zones of DeLee and Charn-
ley10.

The acetabular component were considered loose or if there
was a change in alignment of greater than 5 degrees, more than
5 mm change in position, a circumferential or progressive radi-
olucent line, or shedding of beads from the surface. Migration of
the acetabular component was assessed on sequential radiographs
by comparing the vertical distance from the center of the cup, and
calculated using the integral wire mark, to a horizontal line join-
ing the two anatomical tear drops.

The magnification correction factor (that is, the factor by which
the observed dimension on the radiograph must be multiplied
to obtain the real dimension) was calculated using the formula:
correction factor=known diameter of the implant/apparent radi-
ographic diameter.

As a secondary aspect of this study, the possible radiographic
effects of linear wear and calculated volumetric wear, and there-
fore, debris volume, were assessed. Resorption at the acetabulum
was quantified for statistical analysis as none, mild (present but
<5 mm), moderate (5-10 mm), or severe (>10 mm). The width
of any radiolucent line in the acetabular bone-cement interface
was measured in millimeters. These values were then correlated

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Number of patients</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avascular necrosis</td>
<td>50</td>
<td>82</td>
</tr>
<tr>
<td>Osteoarthritis</td>
<td>7</td>
<td>11.4</td>
</tr>
<tr>
<td>Posttraumatic</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Fracture</td>
<td>2</td>
<td>3.3</td>
</tr>
<tr>
<td>Rheumatoid arthritis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>61</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 1. Initial Diagnosis

Fig. 1. ABG cement free hip prosthesis; the cup is hemispherical
and totally covered with hydroxyapatite.
with the calculated values of linear and volumetric wear.

The results were analyzed statistically, and the influences of the clinical and radiographic variables were studied by using the 2-tailed student t-test, logistical regression, or one-way ANOVA depending on the group characteristics. Results were deemed significant when the value of p was less than 0.05.

RESULTS

1. Clinical results

The clinical results summarized in Table 2 show a marked improvement in total scores versus the preoperative scores. Some postoperative discomfort was present in 18.5% of patients at 5 years, but there was a low incidence of early postoperative thigh pain. In all cases, the pain was mild in intensity, and patients did not need walking aids or analgesics. The percentage of lateral/anterior thigh pain was 2.8% at 5 years. The paired t-test applied to preoperative and postoperative Harris hip scores showed a marked improvement.

2. Radiographic Results

On the acetabular side, 90.2% of cups achieved press-fit stability, but in 9.8% screws had to be used to secure stability. Mean tilt of the acetabular cup was 46.5 degrees (26-61 degrees), and mean anteversion was 11.7 degrees (0.3-37.9 degrees). The mean PE insert thickness used was 9.34 mm (6-13). Mean 2-dimensional linear wear rate was 0.23 mm/year, mean 3-dimensional linear wear rate was 0.26 mm/year, and the mean 3-dimensional volume wear rate was 105.9 mm$^3$/year. The mean direction of head displacement was 0.46 inward, 1.05 upward, and 0.58 forward. Changes in bone structure developed in 54.1% of hips at 5 years. The acetabular polyethylene insert was observed for the first time in 1 hip and at the 5 year visit in other hips. Forty-four hips showed less than 2 mm wear, and 34 hips showed more than 2 mm wear at 5 years.

Fifty-one percents (31 hips) of the 61 hips in our study, all of which were treated with a first-generation cup and a 28 mm diameter head, had osteolysis in the acetabulum, and an acetabular cup position change was observed in 9 hips (14.8%). Acetabular cup position change was present in 7 of 45 hips of spike fixation cups (15.6%), 1 hip in 6 hips (14%) of 2 screw fixation method and 1 hip in 10 hips (10%) of 2 spike and 2 screw fixation both these hips received an autogenous bone graft. Acetabular osteolytic bone lesion was most evident at zone 2 or 3, but not at zone 1. Acetabular fixation by bone ingrowth was evident at zone 1, radiographically, in all 61 hips (100%) at 5 years. We found that the presence of osteolytic lesions was strongly and significantly associated with the increased true wear rates ($p<0.05$). At the five-year follow-up evaluation, osteolysis was seen in 5 of 12 hips (41.7%) with a true wear rate of less than 0.1 mm per year. In contrast, osteolysis occurred in 7 of 19 hips (43%) with a true wear rate between 0.1 and 0.2 mm per year, in 9 of the 14 hips (64.3%) with a wear rate between 0.2 and 0.3 mm per year, and in 9 of 16 hips (56.3%) with a wear rate of greater than 0.3 mm per year.

Linear (2D) and volumetric (3D) wear were both associated with increased lysis of the acetabulum (2D ($p=0.062$), 3D ($p=0.089$)), but were not associated with increased resorption of the femoral neck (2D ($p=0.156$), 3D ($p=0.168$)).

Differences in acetabular loosening between the fixation methods were not significant by one way ANOVA ($p=0.665$), but two of screw fixated acetabular cups that loosened were bone grafted cases. Pearson’s correlation between 2D and 3D wear was 0.857, and was significant at the 0.05 level (2 tailed t-test).

3. Complications

Local complications in the immediate postoperative period included, wound hematomas, superficial sepsis, deep sepsis, and

Table 2. Modified Harris Hip Scores

<table>
<thead>
<tr>
<th>Clinical Parameter</th>
<th>Preoperative</th>
<th>Last follow up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over all score</td>
<td>19</td>
<td>61</td>
</tr>
<tr>
<td>Maximum</td>
<td>79</td>
<td>100</td>
</tr>
<tr>
<td>Minimum</td>
<td>47.2</td>
<td>89.7</td>
</tr>
<tr>
<td>Pain</td>
<td>18.4</td>
<td>39.9</td>
</tr>
<tr>
<td>Gait</td>
<td>22.6</td>
<td>40.5</td>
</tr>
<tr>
<td>Absence of deformity</td>
<td>2.4</td>
<td>3.9</td>
</tr>
<tr>
<td>ROM</td>
<td>3.7</td>
<td>4.9</td>
</tr>
</tbody>
</table>

Fig. 2. A 27-year-old female who was diagnosed as having avascular necrosis of the femoral head and received total hip arthroplasty with the ABG hip system. 5 years and 11 months after operation, her plain radiography showed severe osteolysis of the acetabulum, cup loosening, and severe cup wear despite a well fixed femoral component.
neurological complications. One posterior dislocation could be managed with conservative reposition. One patient sustained a periprosthetic fracture during mobilization and was treated by long stem revision and wiring with an autogeneous bone graft; this fracture healed.

**DISCUSSION**

The short- and mid-term clinical and radiological outcome of the use of HA-coated UHMWP cups was excellent, with survivorship analysis to 14 years showing much better results than non-coated identical cups\(^1\) both clinically\(^1\) and in terms of cup migration\(^1\). A multicenter study revealed that the short term results of the HA-ABG hip system were excellent with the combination of an anatomic stem design with distal overreaming and proximal HA coating\(^3\). Proximal circumferential osseointegration seems to be real, because no linear or distal osteolysis was observed. However, the majority of studies didn’t consider or underestimated acetabular loosening or the wear of HA coated acetabular cup systems, especially clinical reports about HA coated ABG hip systems.

Our incidence of acetabular loosening (14.8%) exceeded that of preliminary studies on HA coated cups\(^5\). In our series, acetabular loosening occurred at a late stage after the cup had functioned well without pain, and shown extensive bony in-growth as far as it could be demonstratred radiologically. This contrasts with porous-coated cups, for which a high incidence of early lucent lines has been reported, suggesting poorer bonding. Most of loosening developed in the spike fixated group (15.7%) than in the screw added group, so we suggest that this is due to a poor locking mechanism.

Despite a well-fixed acetabular cup and bony ingrowth in zone 1 in all hips, osteolysis of zone 2-3 was noted in many hips. Our suggestion about this result is that in the acetabular cup, there are many holes for screw or spike fixation. So, HA particles easily pass to the joint surface through these holes, and osteolysis of the acetabulum occurred around these holes. In addition, the HA coating area is reduced by many holes. Further follow up with closed observation of lytic lesion to determine whether it influences cup stability will be needed.

Polyethylene wear and wear-related complications have become principle reasons for the revision of total hip arthroplasty. Complete wear-through of the polyethylene-bearing surface, catastrophic failure of the insert, and wear-debris-mediated osteolysis are among the most common indications for revision total hip replacement in patients on long-term clinical follow-up. Consequently, analysis of head penetration into the polyethylene liner remains paramount to the study of total hip arthroplasty. From previous studies of femoral head penetration, we have found that computer-assisted measurement methods, examination of serial annual radiographs, and linear regression modeling are necessary for the analysis of the polyethylene wear process.

Our observations of polyethylene wear and acetabular loosening are worse than for cemented\(^10\) and for some cementless cups\(^13,14\). Our results agree with those of Bloebaum et al.\(^4\) and Bloebaum and Dupont\(^2\), who found both HA and metal particles embedded in the polyethylene surface. Metallosis in hips with incomplete polyethylene wear implies third-body wear. The most probable third bodies are particles of HA that detach during insertion, especially from the threads of a screw cup. A human retrieval study has shown osseointegrated HA lamellae\(^6\), which had separated during implantation. HA lost from surfaces uncovered by bone could more easily enter the joint. The poor mechanical properties of thick coatings\(^8\), may also enhance HA abrasion and provide a source of HA particles.

Osteolytic changes of the acetabulum were recorded in 51% of hips around ABG acetabular cups, in which there was considerable wear of the acetabular polyethylene at the five-year radiographic finding. Osteolysis was evident in 5 of the 12 hips (41.7%) with a true wear rate less than 0.1 mm per year. But, osteolysis was evident in 12 of the 31 hips (39%) with an wear rate less than 0.2 mm per year, in 9 of 14 hips (64%) with a wear rate between 0.2 and 0.3 mm per year, and in 9 of 16 hips (56%) with a rate of greater than 0.3 mm per year. Although the occurrence of periprosthetic osteolysis is multifactorial, this relationship supports the hypothesis that osteolysis is a particle-related phenomenon. Our data suggest that osteolysis is directly related to the number of microscopic debris particles generated; low true wear rates may represent a tolerable level of polyethylene particle production, whereas increased true wear rates may represent an amount of particle generation that overwhelms the periprosthetic tissues, eventually resulting in osteolysis. While we are not the first to demonstrate a relationship between wear and osteolysis\(^2,3,10,11,18,20\), our study also involved an examination of serial radiographs of a well controlled patient population and utilized a more refined measurement method. This allowed us to determine long-term true wear rates (not head-penetration rates), and to determine a more precise relationship between wear and osteolysis.

In our cases, osteolysis was found to be in progress in low wear rate hips. So, we believe that the biologic response to wear particles, mainly polyethylene but also including steel and HA, is responsible for the osteolytic lesions and granulomatous cysts. The latter has not been reported previously around HA coated pros-
thesis. The largest lesions were found in cancellous bone. The gap often seen lateral to the proximal part of the stem and could be a route for the transport of particles into the greater trochanter, whereas the hole in the metal backing could have provided access to the acetabular bone. Osteolysis around cementless acetabular components seems to appear most often in hips with abundant particles such as those we encountered. The inflammatory response to an overload of particles probably provokes pain. The well recognized short-term advantages of improved bony ingrowth and ongrowth might ultimately be overtaken by detrimental sequelaes. Further study of joint fluid will be needed to prove third body wear. If aspiration of joint fluid is performed before the revision operation, excessive wear shown by our results due to third body wear by HA particles would be proven. We suggest that the ABG components seem to appear most often in hips with abundant cementless acetabular reconstruction in patients younger than 50 years old. 7 to 11 years results. Clin Orthop 344: 216-226, 1997.

CONCLUSION

Minimum 5 year follow up results of HA coated ABG acetabular cups were disappointing in terms of acetabular osteolysis, a high rate of cup loosening, and excessive polyethylene liner wear despite early accelerated bone remodeling by HA and excellent early clinical results.

REFERENCES

수산화인화석이 도포된 고관절 삽입물의 5년 이상 추시 결과
- 심한 조기 마모와 비구부 골용해 -

박형택·김윤석·정영률·서근택
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목적: HA가 도포된 고관절 전치환술의 비구부의 마모와 해리에 관하여 컴퓨터를 이용한 3차원 기법을 이용한 중기적 추시 경과 관찰을 보고하고자 한다.

대상 및 방법: 1992년 3월부터 1996년 12월까지 수술 받은 52명(61예)을 평균 6년 4개월 경과관찰하였다. 임상적 평가는 Harris 점수를 이용하였고, 수술 직후와 최종 추시 경과 관찰 사진을 컴퓨터에 입력한 후 3차원 기법을 이용하여 2차원과 3차원적 마모를 측정하였다. 비구부의 골 변화는 이전에 발표된 논문들을 따랐다.

결과: 임상적 결과는 수술 전 Harris 점수 47.2점에서 최종 추시상 89.6점으로 나타났다. 경과 관찰상 미지의 대퇴부 동통이 3.6%에서 나타났다. 평균 폴리에틸렌 3차원 선상 마모율은 0.26 mm/year이고, 평균 용적 마모율은 105.9 mm3/year이었다. 16예(26.2%)에서 선형 마모율은 0.3 mm/year 이상(0.30-0.74 mm/year)이었다. 비구의 골용해 소견은 전체 ABG 비구컵의 51%에서 나타났고, 이런 경우에는 심각한 폴리에틸렌 마모의 동반되어 나타났다.

결론: 조기의 증가된 골 재형성과 좋은 임상 결과에도 불구하고 중기 추시상 ABG인공 고관절의 비구부의 변화와 마모 특성은 약간의 실망스러운 결과를 보였다.

색인 단어: 고관절 전치환술, 수산화인화석