



# Average 22-Year Results of Total Hip Arthroplasty Using Harris-Galante Prosthesis in Patients under 50 Years

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**Background:** The Harris-Galante (HG) prosthesis is a first-generation, cementless total hip arthroplasty (THA) prosthesis. Considering the recent increase in the demand for THA in young patients and their life expectancy, a study with a follow-up duration of longer than 20 years in a young population is needed. Therefore, we evaluated the long-term clinical and radiographic results after cementless THA using the HG prosthesis in patients younger than 50 years.

**Methods:** A total of 61 THAs performed using the HG with a minimum follow-up of 10 years were included. There were 38 men and 11 women with an average age of 46 years and the mean follow-up duration was 22 years. Clinical evaluation included modified Harris Hip Score (HHS) and radiographic analysis consisted of cup inclination, anteversion angle, component stability, osteolysis, liner wear rate, wear-through, liner dissociation, and heterotopic ossification. Complications included recurrent dislocation, periprosthetic femoral fracture, and periprosthetic joint infection. Survivorship analysis included cup and stem revision for aseptic loosening, as well as any revision.

**Results:** The HHS improved from 46.5 preoperatively to 81.8 postoperatively ( $p < 0.001$ ). The average linear wear rate was 0.36 mm/yr. A total of 34 hips (56%) were revised: stem revision in 10 (16.4%), cup revision in 9 (14.8%), exchange limited to bearing surface in 8 (13.1%), and revision of all components in 7 (11.5%). Estimated survivorship at 34 years postoperatively was 90.9% for cup revision for aseptic loosening, 80.5% for stem revision for aseptic loosening, and 22.1% for any revision.

**Conclusions:** THA using the HG prosthesis showed satisfactory estimated survivorship of the acetabular and femoral components at 34 years postoperatively with good clinical outcomes. Bearing-related problems, such as osteolysis and liner dissociation, accounted for 56% of revision operations and were concerns in patients younger than 50 years.

**Keywords:** Cementless total hip arthroplasty, Harris-Galante prosthesis, Liner dissociation, Osteolysis, Outcome

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The Harris-Galante (HG) prosthesis, a first-generation, cementless total hip arthroplasty (THA) prosthesis with a porous coating for biological fixation, was introduced in the early 1980s to overcome aseptic loosening and periprosthetic osteolysis following cemented THA.<sup>1)</sup> Although mid-term follow-up results of the HG prosthesis have been reported as satisfactory,<sup>2-5)</sup> studies with a long-term follow-up duration of longer than 20 years are few and limited

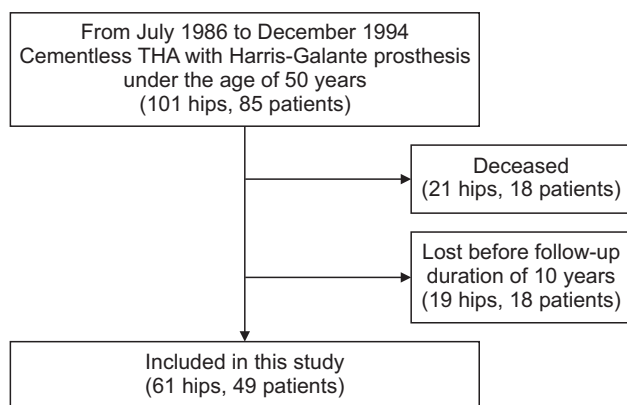
by focusing on the analysis of each acetabular<sup>5)</sup> or femoral component.<sup>6)</sup> Moreover, there are no studies that analyzed long-term outcomes after THA using the HG prosthesis in patients younger than 50 years. The most recently published long-term follow-up study of more than 20 years of the HG prosthesis showed a survival rate of over 80%, but the age of the patient group was 50 years or older.<sup>7,8)</sup> Considering the recent increase in the demand for THA in younger patients and their life expectancy, a longer-term study with a follow-up duration of more than 20 years in a young population is needed.

Therefore, we evaluated the long-term clinical and radiographic results after cementless THA using the HG prosthesis in patients younger than 50 years, including estimated survivorship at 34 years postoperatively. In this analysis, we set cup revision for aseptic loosening, stem revision for aseptic loosening, and revision for any reason as the endpoints.

## METHODS

### Demographics

This study obtained approval from Kyungpook National University Hospital Institutional Review Board (IRB No. KNUH 2020-05-057). Informed consent was waived because of the retrospective nature of this study. From July 1986 to December 1994, 85 patients (101 hips) younger than 50 years underwent cementless THA using the HG prosthesis. During the study period, 18 patients (21 hips) died from causes unrelated to surgery, and 18 patients (19 hips) were lost before the 10-year follow-up. Among them, no patient had a revision before they were lost to follow-



**Fig. 1.** Flowchart for recruitment of patients who underwent cementless total hip arthroplasty (THA) using the Harris-Galante prosthesis and were followed up for at least 10 years.

up. Thus, we included 61 hips in 49 patients (38 men and 11 women) in this study (Fig. 1). The average radiographic follow-up duration was 22.0 years (range, 10–34.4 years). Table 1 details the patient demographics.

### Surgical Data

All THAs were performed using a cementless prosthesis of identical design using the posterolateral approach. The HG porous cup was hemispherical with titanium fiber-mesh coating and multiple screw holes that used 3–4 tines to lock the modular polyethylene liner into place.<sup>5)</sup> The HG femoral stem had a straight cylindrical design with a collar and 3 proximal noncircumferential titanium fiber-mesh pads, excluding the lateral side, and 4 flutes in the distal part to enhance rotational stability.<sup>6)</sup> A 28-mm metal head and conventional polyethylene (CPE) articulation were used in all patients. Postoperative rehabilitation included non-weight-bearing ambulation for 6 weeks, followed by gradually increased weight-bearing for an additional 6 weeks.

### Clinical Evaluation

Patients visited the outpatient clinic at 6 weeks, 3 months, 6 months, and 1 year postoperatively and annually thereafter; the modified Harris Hip Score (HHS) was evaluated at each visit.<sup>9)</sup>

**Table 1.** Patient Demographics

Variable	Value
Sex (hip)	
Male	49 (80.3)
Female	12 (19.7)
Height (m)	1.64 (1.46–1.77)
Weight (kg)	62.1 (46.3–78.5)
Body mass index (kg/m <sup>2</sup> )	23.2 (17.6–29.3)
Age at operation (yr)	45.8 (26.3–49.1)
Diagnosis (hip)	
Osteonecrosis of the femoral head	43 (70.5)
Rheumatoid arthritis	5 (8.2)
Hip dysplasia	3 (4.9)
Ankylosing spondylitis	3 (4.9)
Primary osteoarthritis	3 (4.9)
Others	4 (6.6)

Values are presented as number (%) or mean (range).

### Radiographic Evaluation

Serial radiographs including anteroposterior and oblique views of the pelvis were taken at each visit and analyzed by two independent orthopedic surgeons (HW and SHB). Radiographic evaluation included cup inclination and anteversion angle,<sup>3)</sup> component stability,<sup>10,11)</sup> osteolysis,<sup>12)</sup> wear-through,<sup>13)</sup> liner dissociation,<sup>7)</sup> heterotopic ossification (HO),<sup>14)</sup> and liner wear rate.<sup>15)</sup> A computed tomography (CT) scan was performed in 44 patients (72.1%) to evaluate osteolysis. The anteversion angle of the cup and the wear rate of the CPE liner were measured using digital imaging software (PolyWare Draftware Developers Inc., Vevay, IN, USA) with edge detection on plain radiographs.<sup>15)</sup>

### Complications

Complications included recurrent dislocation, postoperative periprosthetic femoral fracture (PFF),<sup>16)</sup> periprosthetic joint infection (PJI), reoperation, and revision.

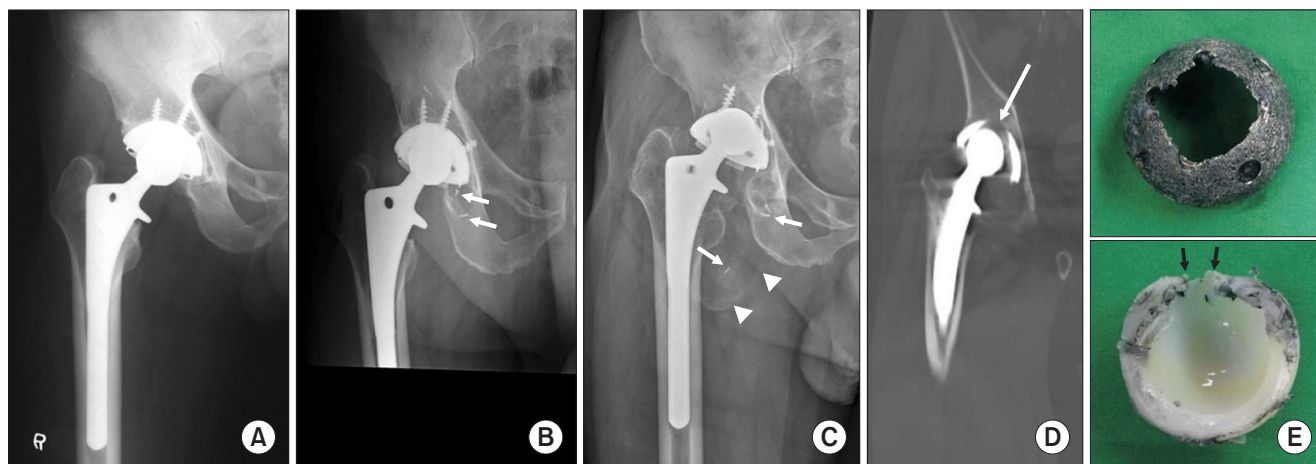
### Statistical Analysis

We compared the preoperative and final HHS using the Student *t*-test. Logistic regression analysis analyzed the causes of loosening, osteolysis, and wear-through. Multivariable regression analysis identified the correlation between the liner wear rate and the variables. Kaplan–Meier analysis estimated survivorship, with the endpoints defined as (1) cup revision for aseptic loosening, (2) stem revision for aseptic loosening, and (3) any revision at 34

years postoperatively. We also calculated the 95% confidence interval (CI). We used SAS ver. 9.4 (SAS Institute, Cary, NC, USA) for all statistical analyses, with statistical significance set at  $p < 0.05$ .

## RESULTS

The mean HHS improved from 46.5 preoperatively to 81.8 postoperatively ( $p < 0.001$ ). Radiographs taken immediately after THA revealed an average inclination angle of 38.1° (range, 27.1°–51.6°) and an anteversion angle of the cup of 27.3° (range, 2.4°–56.8°). Aseptic loosening was shown in 19 hips (31.1%): cup loosening in 7 (11.5%), stem loosening in 13 (21.3%), and both stem and cup loosening in 1 hip. Loosening was associated with body mass index (BMI; odds ratio [OR], 2.23; 95% CI, 1.34–3.67;  $p = 0.013$ ). Osteolysis was demonstrated in 49 hips (80.3%): 35 (57.4%) in the periacetabular area, 43 (70.5%) in the proximal femur, and 29 (47.5%) in both the femur and pelvis. Osteolysis was not associated with age, sex, BMI, inclination, and anteversion angle of the cup ( $p > 0.05$ ). The liner wear rate was 0.36 mm/yr (range, 0.13–0.8 mm/yr) and was not associated with the variables. Wear-through occurred in 6 hips (9.8%) and liner dissociation was noted in 2 hips (3.3%) (Fig. 2). Wear-through was related to age (OR, 0.846; 95% CI, 0.541–0.983;  $p = 0.011$ ) but not to the other variables. Liner dissociation was not associated with the variables. HO was classified as grade I in 1 hip (1.6%) and was not related to pain or functional limitation.



**Fig. 2.** Plain radiographs of a 49-year-old man who underwent total hip arthroplasty (THA) using the Harris-Galante prosthesis due to osteonecrosis of femoral head in his right hip. (A) A postoperative anteroposterior radiograph. (B) A radiograph taken at 23 years after THA demonstrated broken tines (white arrows), indicating locking mechanism failure, but the patient refused revision surgery. (C) A radiograph taken at 26 years postoperatively showed acetabular cup penetration by the femoral head, osteolysis in Gruen zone 7, and the “bubble sign” (arrowheads) due to metallosis. (D) A coronal computed tomography scan showed that the dome of the acetabular cup was not visible (white arrow). (E) Photographs of a perforated acetabular cup and wear-through of a dissociated polyethylene liner (black arrows).

PFF was observed in 9 hips (14.8%): 5 (8.2%) type A<sub>G</sub>, 2 (3.3%) type B1, and 1 type B2, and 1 type C1. All PFFs healed without further event. In 4 hips with type A<sub>G</sub>, PFF obtained union by conservative treatment, while in 1 hip with type A<sub>G</sub> and all hips with type B1 and type C1, PFF underwent open reduction and internal fixation. For 1 hip with type B2 PFF, stem revision was performed. Recurrent dislocation occurred in 2 hips (3.3%): 1 patient with recurrent dislocation showed stem loosening and underwent revision of stem and articulation while the other patient had osteolysis and underwent articulation change. Both had no dislocation thereafter. PJI was noted in 2 hips (3.3%). They underwent two-stage revision at 10 and 12.9 years after primary THA, respectively.

Overall, 38 reoperations (62.3%) were performed including 34 revisions (55.7%): stem revision in 10 (16.4%), cup revision in 9 (14.8%), exchange limited to bearing surface in 8 (13.1%), and all component revision in 7 (11.5%) (Table 2). The femoral stem was revised in 17 hips (27.9%): aseptic loosening in 8 (13.1%), osteolysis in 6 (9.8%), PJI in 2 (3.3%), and PFF in 1 hip. The acetabular cup was revised in 16 hips (26.2%) because of osteolysis in 8 (13.1%), loosening in 5 (8.2%), liner dissociation in 2 (3.3%), and PJI in 1 hip. Nineteen hips (31.1%) were revised due to problems related to bearing surface: osteolysis in 17 and liner dissociation in 2 hips. There was no re-revision surgery during the study period. The remaining 4 cases of reoperation were internal fixation for type B1 PFF in 2, type A<sub>G</sub> PFF in 1, and type C1 PFF in 1 hip.

### Survivorship

Using the Kaplan-Meier analysis, the estimated survival rate was 90.9% (95% CI, 79.3%–96.1%) with cup revision for aseptic loosening as the endpoint at 34 years postoperatively (Fig. 3A) and 80.5% (95% CI, 64.9%–89.7%) with stem revision for aseptic loosening as the endpoint at the same time point (Fig. 3B). Using any revision as the endpoint, survivorship was 22.1% (95% CI, 8.2%–40.3%) at 34 years postoperatively (Fig. 3C).

## DISCUSSION

Overall, our study showed satisfactory performance of the acetabular and femoral components, with an estimated survivorship of 90.9% and 80.5%, respectively, with revision for aseptic loosening as the endpoint, poor estimated survivorship of 22.1% with any revision as the endpoint at 34 years postoperatively, a good clinical score of 81.8 points, and a high prevalence of osteolysis in 49 hips (80.3%) at an average follow-up duration of 22 years.

The cup survival rate in our study was 90.9% for cup revision caused by aseptic loosening at the endpoint of 34 years postoperatively, which is comparable to the results of previous long-term studies (Table 3).<sup>2,4,7,8</sup> Saito et al.<sup>7</sup> reported a survivorship of 92.1% for cup revision for any reason at a mean follow-up duration of 22.5 years in 38 hips, and Kawamura et al.<sup>8</sup> showed survivorship of 90.3% for any cup revision at an average follow-up duration of 24.6 years in 49 hips. Several factors may have contributed to these favorable results: a titanium fiber-mesh, porous-coated surface,<sup>7</sup> and method of bone preparation.<sup>2</sup> We speculate that the cup design with porous-coated outer surface with titanium fiber-mesh and holes for screw fixation might have promoted rigid initial fixation and durable bone in-growth, resulting in this excellent long-term outcome.

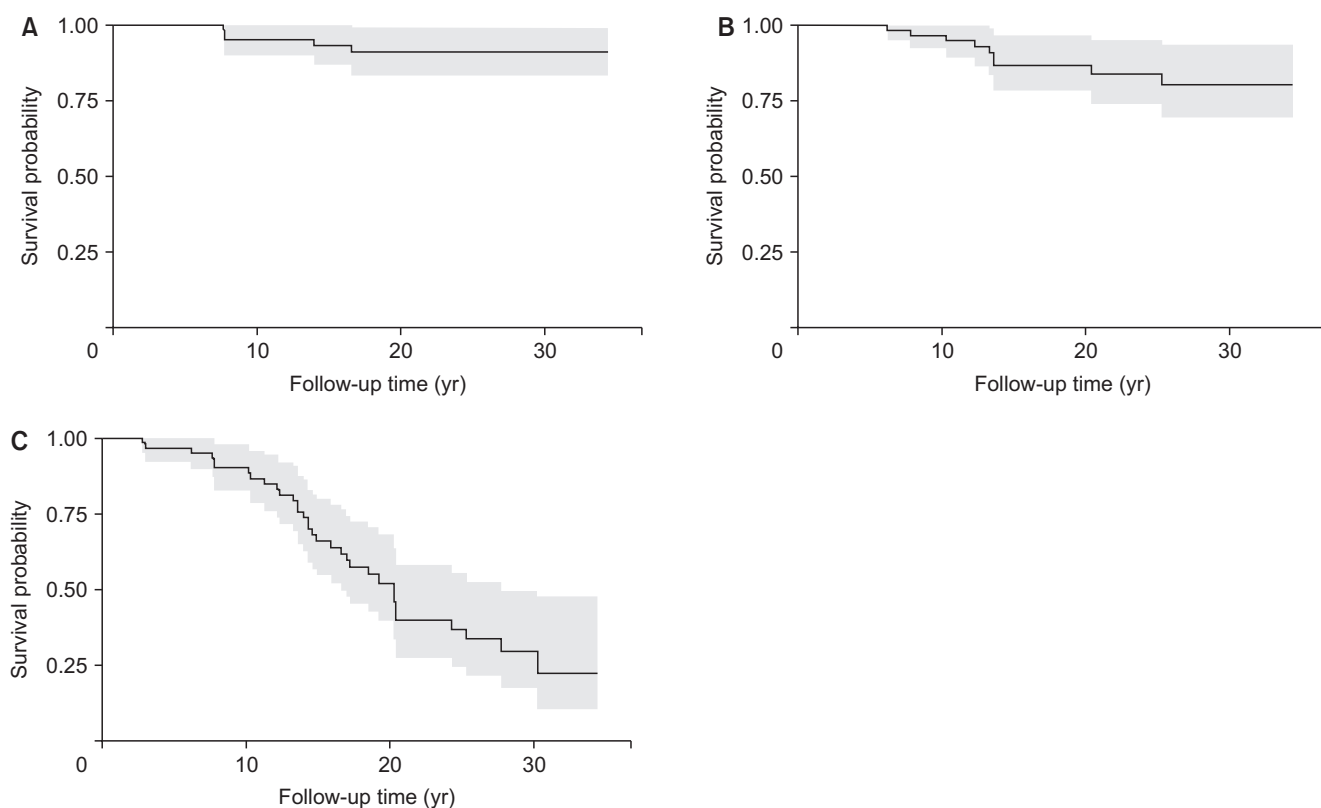
The femoral component showed less favorable survivorship of 80.5% for stem revision due to aseptic loosening at 34 years postoperatively when compared to that of the acetabular component. This is also similar to the results of previous studies with a follow-up duration of 15–18 years, although some studies with longer duration but fewer patients have shown better survivorship of 94.3% at 22.5 years<sup>7</sup> and 86.4% at 24.6 years postoperatively<sup>8</sup> (Table 3). We hypothesized that the reason for less favorable results of the femoral stem than the acetabular cup might in part from the stem design; the noncircumferential fiber-mesh pads absent on the lateral surface<sup>7,8</sup> and poor femoral filling<sup>3</sup> as wear particles could enter the femoral canal along with the joint fluid and cause distal femoral osteolysis or aseptic loosening.<sup>17</sup> Aseptic loosening was positively correlated with BMI (OR, 2.23) in our study, which previous studies pointed out as a risk factor for aseptic loosening.<sup>18</sup>

Linear wear, osteolysis, and wear-through related to bearing surface are concerns. Catastrophic failure including wear-through and liner dissociation occurred in 8 hips (13.1%). Our study demonstrated a liner wear rate of 0.36 mm/yr, prevalence of osteolysis in 80.5%, and a wear-through rate of 9.8%. We also found that wear-through was negatively correlated with age (OR, 0.846), meaning that younger patients are more susceptible to wear and related complications. Liner wear rate and prevalence of osteolysis after THA using the HG prosthesis have been reported to range from 0.09 to 0.17 mm/yr<sup>3,4,7,19</sup> and from 5.2% to 60%, respectively.<sup>2,4,6-8,19</sup> Hallan et al.<sup>20</sup> have reported 48% osteolysis at a 12-year follow-up of 25 hips with an average patient age of 47 years, and Utting et al.<sup>5</sup> have shown a survival rate of 55.3% when impending osteolysis was the endpoint as a result of following 13.6 years of 70 hips with an average patient age of 40 years. We speculate that the

**Table 2.** Summary of Revisions

Case number	Sex	Diagnosis	Age at surgery (yr)	Interval to revision (yr)	Component	Reason for revision
1	Male	Dysplasia	48.8	7.9	Cup	Loosening
2	Male	ONFH	45.8	8.2	All	Loosening
3	Male	ONFH	49.9	10.0	Stem	PFF B2
4	Male	ONFH	42.6	10.0	All	PJI
5	Male	OA	48.3	10.0	Cup	Loosening
6	Male	ONFH	48.8	10.1	Stem	OL
7	Male	ONFH	47.1	10.3	Stem	Loosening
8	Male	ONFH	48.9	11.4	All	OL
9	Male	ONFH	48.3	12.2	Stem	OL
10	Male	ONFH	36.3	12.3	All	Stem loosening, cup OL
11	Male	ONFH	47.5	12.9	Stem	PJI
12	Male	ONFH	29.8	13.3	Stem	Loosening
13	Male	ONFH	49.3	13.6	Stem	Loosening,
14	Male	ONFH	48.7	13.7	Stem	Loosening
15	Male	ONFH	41.6	14.0	Cup	Loosening
16	Female	ONFH	29.8	14.3	Cup	OL
17	Female	ONFH	46.3	14.4	Articulation	OL
18	Male	AS	49.1	14.5	Cup	OL
19	Male	ONFH	48.2	14.9	Articulation	OL
20	Male	ONFH	42.4	15.3	Stem	Loosening
21	Male	ONFH	42.2	16.0	Articulation	OL
22	Male	ONFH	38.3	16.7	Cup	Loosening
23	Female	RA	49.1	17.2	Articulation	OL
24	Male	ONFH	49.9	18.5	Articulation	OL
25	Male	AS	35.3	19.0	All	OL
26	Male	ONFH	45.8	20.3	Articulation	OL
27	Male	ONFH	48.5	20.5	Stem	Loosening
28	Male	ONFH	30.5	20.5	All	Stem OL, cup LD
29	Male	ONFH	30.4	20.6	All	OL
30	Male	ONFH	49.9	21.0	Cup	OL
31	Male	ONFH	48.5	24.4	Cup	LD
32	Male	ONFH	48.3	26.8	Cup	OL
33	Female	Dysplasia	44.0	27.8	Articulation	OL
34	Female	PA sequelae	42.1	30.4	Articulation	OL

ONFH: osteonecrosis of the femoral head, PFF: periprosthetic femoral fracture, PJI: periprosthetic joint infection, OA: osteoarthritis, OL: osteolysis, AS: ankylosing spondylitis, RA: rheumatoid arthritis, LD: liner dissociation, PA: pyogenic arthritis.



**Fig. 3.** The Kaplan-Meier survivorship curve for the Harris-Galante prosthesis. (A) Survivorship with cup revision for aseptic loosening as the endpoint. (B) Survivorship with stem revision for aseptic loosening as the endpoint. (C) Survivorship with revision for any reason as the endpoint.

**Table 3.** Comparison with Previous Studies after Total Hip Arthroplasty Using the Harris-Galante Prosthesis

Study	Hip	Age (yr)	Follow-up period (yr)	Osteolysis (%)	Survival rate (%)			
					Year	Cup*	Stem*	Any revision
This study	61	45.8	22.0 (10–34)	80.5	34	90.9	80.5	22.1
Parvizi et al. <sup>2)</sup>	90	57.5	14.9 (12–18)	12.2	15	91.9	82	NA
Anseth et al. <sup>4)</sup>	60	54	17.9 (15–20)	13.3	20	97.4	90	87.7
Saito et al. <sup>7)</sup>	38	51.2	22.5 (19–25)	5.2	22.5	92.1 <sup>†</sup>	94.3 <sup>†</sup>	86.8
Kawamura et al. <sup>8)</sup>	49	54	24.6 (21–27)	50	24.6	90.3 <sup>†</sup>	86.4	87

Values are presented as average (range) unless otherwise indicated.

NA: not applicable.

\*Evaluated with aseptic loosening of each component as the endpoint. <sup>†</sup>Evaluated with revision for each component as the endpoint.

higher rate of linear wear and osteolysis in our study might have originated from accelerated polyethylene wear due to the relatively longer follow-up duration. Previous studies have shown that wear debris accumulation and progressive oxidation in long-term follow-up of THA can accelerate polyethylene wear.<sup>21)</sup> Also, the higher proportion of young, active men with osteonecrosis of the femoral head (ONFH) and the use of more accurate methods to identify

osteolysis including both oblique views of plain radiographs and CT scans<sup>22)</sup> might have affected the higher rate of osteolysis in our study.<sup>23)</sup> Liner dissociation (3.3%) is another concern. Failure of locking mechanism has been reported to lead to polyethylene liner dissociation.<sup>6,19)</sup> *In vivo* oxidative degradation,<sup>24)</sup> the weak locking mechanism of the HG cup,<sup>25)</sup> and the existence of a gap between the liner and the HG cup<sup>26)</sup> might contribute to failure of the

locking mechanism, exacerbating liner wear by a third-body mechanism.<sup>27)</sup> In addition, we speculate that the liner rim elevated over the margin of the acetabular cup might increase the risk of impingement with the stem trunnion damaging the locking mechanism, particularly in young, active Asian men with a cultural habit of squatting.<sup>28)</sup>

Survivorship with revision for any reason as the endpoint was 22.1% at 34 years in our study, and 19 of 34 revisions (55.9%) originated from bearing surface problems. The survivorship longer than 20 years after THA in patients younger than 50 years are variable. To our knowledge, the longest follow-up study performed in those younger than 50 years showed estimated survivorship of 57% for any revision at 28 years after cementless THA using the CLS Spotorno stem and variable acetabular cups with 32-mm ceramic-on-CPE articulation.<sup>29)</sup> The higher rate of revision related to bearing surface and resultant worse survivorship for any revision in our study might in part be associated with the relatively longer follow-up duration, demographic characteristics (young, active men), insufficient locking mechanism, and the use of thinner liners due to the smaller size of the acetabular component (average 52.6 mm).<sup>24)</sup> Also, sterilization in the presence of air and poor quality of the previous-generation polyethylene liner might be one of the reasons for worse performance of the bearing surface after THA using the HG prosthesis.<sup>24)</sup>

Although the HHS improved significantly in our study ( $p < 0.001$ ), the score of 81.8 points at the last follow-up visit can be categorized as “good.” We speculate that this score resulted from the higher prevalence of reoperation (38 hips, 62.3%), of patients with aseptic loosening who refused revision THA (7 hips, 11.5%), and of comorbidity with aging during the follow-up of over 20 years.

Our study has several limitations. First, this retrospective study examined the implants commercially withdrawn from the market. However, when new implants are introduced into clinical practice, comparisons with previous-generation prostheses are important, and our study may provide useful information to overcome the drawbacks of the previous product and determine the value of

a new one. Second, comparison among different implants would provide stronger evidence. Third, the majority of the patients were young, active men, and ONFH was the most common reason for THA. Thus, we cannot extend our conclusions to the elderly population. Fourth, there was no re-revision surgery within the follow-up period, but 18 hips (52.9%) had follow-up loss or death after revision surgery among a total of 34 revisions. Therefore, caution is required in interpreting the results. Finally, the wear rate threshold for osteolysis in THA using CPE is known to be 0.1 mm/yr.<sup>30)</sup> In this study, the average wear rate was 0.36 mm/yr, and osteolysis was demonstrated in 80.5%, but unfortunately, the threshold between osteolysis and wear rate could not be found. Nevertheless, this study is based on one of the longest follow-up durations in patients younger than 50 years. In addition, all patients underwent THA using a prosthesis with the identical design and visited the clinic in person to take radiographic evaluation during the whole follow-up period.

In conclusion, THA using the HG prosthesis showed favorable estimated survivorship of the acetabular and femoral components at 34 years postoperatively with good clinical outcomes. Bearing-related problems, such as osteolysis and liner dissociation, consisted of 56% of revision operations and were concerns in patients younger than 50 years.

## CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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