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Concerns with alumina bipolar hemiarthroplasties compared to metal bipolar hemiarthroplasties when performed for nontraumatic osteonecrosis of the femoral head

Seneki Kobayashi^{1,2} · Nobuhiko Sugano^{1,3} · Wataru Ando^{1,3} · Wakaba Fukushima^{1,4} · Kyoko Kondo⁵ · Takashi Sakai^{1,6}

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Abstract

Purpose A nationwide multicenter follow-up cohort study of hip replacement arthroplasties performed for nontraumatic osteonecrosis of the femoral head (ONFH) aimed to answer the following questions: What factors were associated with need for reoperation? Although many modifications were made in bipolar hemiarthroplasties (BPs) to improve their durability, could we find any evidence of their efficacy?

Methods Excluding 58 infected hips and 43 ABS THAs with very poor survivorship, we analyzed 7393 arthroplasties; 6284 total hip arthroplasties (THAs), 886 BPs, 188 total resurfacing arthroplasties, and 35 hemi-resurfacing arthroplasties (hRSs). In the 886 BPs, 440 hips had a smooth small-diameter prosthetic neck (nBPs), 667 hips had a smooth neck (sBPs), 116 hips had highly cross-linked polyethylene in the outer head (hBPs), and 238 hips had an outer head whose outer surface was alumina ceramic (aBPs) (648 hips had an outer head whose outer surface was metal [mBPs]). Multivariate analyses using a Cox proportional-hazard model analyzed risk factors.

Results Follow-up ranged from 0.1 to 27 (average, 6.9) years, during which 265 hips (3.6%) needed reoperation. Combined systemic steroid use and excessive alcohol consumption and lateral approach were associated with higher risks, aBPs were less durable than THAs or mBPs, and hRSs were inferior to the others. Regarding BPs, the following divisions did not influence their survivorship; nBP or not, sBP or not, and hBP or not.

Conclusions Factors associated with reoperation risk were identified as described above. The modifications made in BPs did not improve their durability, but aBPs made it worse.

Level of clinical evidence Level III, therapeutic cohort study.

Keywords Osteonecrosis of the femoral head (ONFH) \cdot Hip arthroplasty \cdot Bipolar hemiarthroplasty \cdot Resurfacing \cdot Survival rate

Seneki Kobayashi seneki@suwa.jrc.or.jp

- ¹ The Investigation Committee on Osteonecrosis of the Femoral Head under the Ministry of Health, Labour and Welfare of Japan, Tokyo, Japan
- ² Department of Orthopaedic Surgery, Suwa Red Cross Hospital, 5-11-50 Kogandoori, Suwa-city 392-8510, Naganoprefecture, Japan
- ³ Department of Orthopaedic Medical Engineering, Osaka University Graduate School of Medicine, Suita-city, Osakaprefecture, Japan
- ⁴ Department of Public Health, Osaka Metropolitan University Graduate School of Medicine, Osaka-city, Osaka-prefecture, Japan
- ⁵ Research support platform, Osaka Metropolitan University Graduate School of Medicine, Osaka-city, Osaka-prefecture, Japan
- ⁶ Department of Orthopedic Surgery, Yamaguchi University Graduate School of Medicine, Ube-city, Yamaguchiprefecture, Japan

Introduction

Nontraumatic osteonecrosis of the femoral head (ONFH) patients who underwent hip replacement arthroplasties were generally younger, more of male gender [1], and at higher risks of postoperative dislocation [2, 3] and need for reoperation [4-8], compared with patients who underwent the procedures mainly for osteoarthrosis (OA). Hip arthroplasty practice has changed noticeably, e.g., increasing employment of total hip arthroplasty (THA) with highly (approximately 10 Mrad) cross-linked polyethylene (HXLPE) and a larger prosthetic head. Therefore, hip replacement arthroplasties performed for OFNH should be monitored, which was conducted by a nationwide multicenter follow-up cohort study. This is the largest prospective follow-up cohort study of primary hip replacement arthroplasties performed for ONFH, to our knowledge. Each patient was registered and prospectively followed up clinically and radiographically at each institution.

Bipolar hemiarthroplasties (BPs) have been done for ONFH usually before development of OA. Many modifications were made to improve their poor results [9, 10]. Because osteolysis due to polyethylene debris generated by neck-outer head impingement was a major concern in BP [11, 12], a new type of BPs (nBPs) with a smooth, smalldiameter (approximately 10 mm) neck without any sharp corners began to take place of the other BPs (oBPs) [1]. As contemporary femoral prostheses tended to have a neck with a larger diameter, 'small-diameter' was excluded from the definition, which described BPs with a smooth neck (sBPs) and the others with a rough surfaced neck (rBPs). Alumina BPs (aBPs, the outer surface of the outer head was made of alumina ceramic) and BPs with HXLPE in the outer head (hBPs) were also developed to surpass the durability of metal BPs (mBPs) and BPs with conventional polyethylene (cPE) in the outer head (cBPs), respectively. However, their efficacy has not been proven clinically.

Research questions of this study were: What factors were associated with need for reoperation? Although many modifications were made in BPs to improve their durability, could we find any evidence of their efficacy?

Materials and methods

Nationwide multicenter follow-up cohort study of hip replacement arthroplasties performed for ONFH

The Investigation Committee on ONFH under the auspices of the Ministry of Health Labour and Welfare set up a nationwide multicenter follow-up cohort study of primary hip replacement arthroplasties performed for ONFH to clarify patient features, operative parameters, and followup status of arthroplasties including need for reoperation. Hip surgeons at 31 institutions participated in the study. We studied the procedures performed for ONFH or OA secondary to ONFH between January 1996 and December 2022. Diagnosis and staging of ONFH was made according to the criteria of the committee [13, 14]. Definitions of ONFH stages 1, 2, 3, and 4 were in line with those of Ficat Stages I, II, III, and IV [15] and with ARCO (Association Research Circulation Osseous) stages I, II, III, and IV [16]. Primary hip arthroplasties that replaced all or part of the hip joint with artificial materials were included; i.e., THA, BP, total resurfacing arthroplasty (tRS), and hemiresurfacing arthroplasty (hRS). Demographic (age, gender, height, weight, BMI [body mass index], ONFH-associated factors, ONFH stage, and previous surgery in the index hip joint) and surgery-related (approach, type of surgery, acetabular and femoral components, material of the acetabular articulating surface, material and diameter of the prosthetic head) data were recorded. Follow-up data included need for reoperation.

Arthroplasties analyzed for factors related to need for reoperation

From the entire cohort of 7494 hips, 58 infected hips (0.77%) were excluded. We also excluded 43 hips treated with ABS THA (Kyocera, Kyoto, Japan) which had a thin alumina liner supported by polyethylene in a socket. In the present study, they had a very low survival rate (62% at ten years and 55% at 15 years). Poor survivorship of ABS THAs was reported previously [17]. The remaining 7393 hips were analyzed for reoperation risk. Patient age at surgery ranged from 14 to 98 (average, 51.3) years, and 55.3% were in male patients. Height ranged from 132.0 to 193.5 (average, 162.4) cm. Weight ranged from 27.0 to 130.0 (average, 61.4) kg. BMI ranged from 11.6 to 43.9 (average, 23.18) kg/m². The ONFH-associated factors were systemic steroid use in 58.9%, excessive alcohol consumption 28.2%, none of them 10.5%, and both of them 2.4%. ONFH stage 3 (collapse of the femoral head without joint-space narrowing) was in 55.6%, stage 4 (OA) 41.5%, and stage 2 (without collapse of the femoral head) 2.9%. While 92.5% had no previous surgery, 7.5% had been treated with miscellaneous joint-preserving procedures.

The surgical approach was posterior in 62.3% (4605 hips), anterior or anterolateral 19.4% (1437 hips), and lateral 18.3% (1351 hips). Minimum incision surgery (MIS) was employed in 27.6% and conventional incision in 72.4%. THA was performed in 85.0% (6284 hips), BP 12.0% (886 hips), tRS 2.5% (188 hips), and hRS 0.5% (35 hips). The 886 BPs could be divided as follows; 440 nBPs (49.7%) and 446

oBPs (50.3%), 667 sBPs (75.3%) and 219 rBPs (24.7%), 116 hBPs (13.1%) and 770 cBPs (86.9%), and 238 aBPs (26.9%) and 648 mBPs (73.1%). The alumina and the metal outer heads had the same taper junctions, and either of them could be used at surgeons' choice. Finish of the outer surface of the acetabular component was porous coating with hydroxyapatite (HA) over-coating (48.1%), porous coating without HA (36.7%), etc. (15.2%). The acetabular component was fixed without cement in 85.6% and with cement in 1.9% (hemiarthroplasty in 12.5%). Surface finish of the stem was porous coating with HA (40.7%), porous coating without HA (28.7%), polished cement stem (8.7%), etc. (21.9%). The femoral component was fixed without cement in 83.7% and with cement in 16.3%. Material of the articulating surface of the acetabular component was HXLPE (53.8%), moderately (5 to 7.5 Mrad) cross-linked polyethylene (18.4%), cPE (17.9%), cobalt-chrome (6.2%), ceramic (3.2%), and hRS (0.5%). Material of the prosthetic head was ceramic (59.5%), cobalt-chrome (33.4%), oxidized zirconium (5.0%), and stainless steel (2.1%). The head diameter was 32 mm in 31.0%, 28 mm 22.5%, ≥ 36 mm 21.3%, 26 mm 16.2%, and 22 mm 9.0%.

Statistical analyses

Factors related to need for reoperation were analyzed with a Cox proportional-hazard model using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). Univariate analyses were first performed applying the model to each of the demographic and operative parameters with a significance level of p < 0.1. Parameters with p < 0.1 were then examined together using the model with a significance level of p < 0.05 (multivariate analysis). Effects of the identified risk factors on survivorship of hip arthroplasties were illustrated with the Kaplan-Meier estimator (with log-rank tests), using IBM SPSS statistics version 29 (IBM Corp, Armonk, NY, USA), with a significance level of p < 0.05. In the 7393 hips, 311 hips (4.2%) were in 244 patients who died during follow-up, which allowed results obtained with the estimator as they were [18].

Ethical approval

Ethical approvals for this study were comprehensively obtained at three representative institutions. The procedures in the study adhered to the tenets of the Declaration of Helsinki.

Results

Multivariate survivorship analyses

Follow-up ranged from 0.1 to 27 (average, 6.9) years, during which 265 hips (3.6%) needed reoperation (Table 1). The multivariate survivorship analysis identified ONFHassociated factor, surgical approach (direction), and type of surgery as risk factors (Table 2). Combined systemic steroid use and excessive alcohol consumption had a higher risk, with no associated factors as reference (p=0.004). Compared with posterior approach, lateral approach had a higher risk (p=0.008). With THAs as reference, BPs were

Table 1 Reasons for need for reoperation which was required in 265 hips in the 7393 hip arthroplasties	Reasons for need for reoperation	Number of hips (265 hips in total)	
	recurrent dislocations	61 hips (0.83% of the 7393 hips, 57 THAs and 4 BPs)	
	proximal migration of the outer head of BP	30 hips (0.41%, 30 BPs)	
	periprosthetic femoral fracture	29 hips (0.39%, 26 THAs and 3 BPs)	
	osteolysis	26 hips (0.35%, 26 THAs)	
	stem loosening	21 hips (18 THAs and 3 BPs)	
	polyethylene liner wear and/or breakage	21 hips (21 THAs)	
	socket loosening	14 hips (14 THAs)	
	pain	12 hips (7 BPs, 3 hRSs, 1 THA, and 1 tRS)	
	adverse reaction to metal debris 10 hips (8 metal-on-metal THA on-MXLPE THA, and 1 tRS)		
	proximal migration of hRS	8 hips (8 hRSs)	
	loosening of the femoral prosthesis in RS	7 hips (6 tRSs and 1 hRS)	
	femoral neck fracture in RS	5 hips (4 tRSs and 1 hRS)	
	impingement of iliopsoas tendon	5 hips (3 THAs and 2 tRSs)	
	stem fracture	4 hips (4 THAs)	
<i>THA</i> , total hip arthroplasty; <i>BP</i> , bipolar hemiarthroplasty; <i>tRS</i> , total resurfacing arthroplasty; <i>hRS</i> , hemi-resurfacing arthro- plasty; <i>MXLPE</i> , moderately cross-linked polyethylene	socket and stem loosening	3 hips (3 THAs)	
	ectopic ossification	3 hips (1 THA and 2 hRSs)	
	ceramic head breakage	2 hips (2 THAs)	
	femoral fracture distal to thrust plate	2 hips (2 THAs)	
	others (1 for each)	2 hips (2 THAs)	

Table 2Multivariate analysisusing the Cox proportional-haz-ard model for factors related toneed for reoperation in the 7393hip arthroplasties

Parameter	Reference	Factor	Hazard ratio (95% CI)	<i>p</i> -value
ONFH-associated factor	none	systemic steroid use	1.17 (0.73–1.87)	0.517
		excessive alcohol consumption	1.44 (0.87–2.36)	0.155
		both	3.00 (1.43-6.28)	0.004
Surgical approach (direction)	posterior	anterior or anterolateral	0.64 (0.36-1.12)	0.116
		lateral	1.50 (1.11-2.02)	0.008
Surgical approach (incision length)	conventional	MIS	0.75 (0.50–1.14)	0.184
Type of surgery	THA	BP	1.06 (0.76–1.49)	0.734
		tRS	2.08 (1.08-4.03)	0.030
		hRS	9.01 (4.62–17.58)	< 0.0001
Femoral fixation	non-cement	cement	0.98 (0.64–1.49)	0.917

CI, confidence interval; *MIS*, minimum incision surgery; *THA*, total hip arthroplasty; *BP*, bipolar hemiarthroplasty; *tRS*, total resurfacing arthroplasty; *hRS*, hemi-resurfacing arthroplasty

Table 3Multivariate analysisusing the Cox proportional-hazard model for factors relatedto need for reoperation in the7393 hip arthroplasties, with BPsdivided into aBPs and mBPs

CI, confidence interval; *MIS*, minimum incision surgery; *THA*, total hip arthroplasty; *BP*, bipolar hemiarthroplasty, *aBP*, BP with an alumina outer head; *mBP*, BP with a metal outer head, *tRS*, total resurfacing arthroplasty; *hRS*, hemi-resurfacing arthroplasty Parameter Reference Factor Hazard ratio (95% p-value CI) ONFH-associated systemic steroid use 1.16 (0.72–1.86) 0.535 none factor 1.43 (0.87-2.35) 0.163 excessive alcohol consumption both 2.97 (1.42-6.21) 0.004 Surgical approach posterior anterior or anterolateral 0.64(0.37 - 1.13)0.125 (direction) lateral 1.52 (1.12-2.05) 0.007 Surgical approach MIS 0.76 (0.50-1.15) 0.194 conventional (incision length) Type of surgery THA aBP 1.82 (1.12-2.94) 0.016 mBP 0.82 (0.54-1.24) 0.347 tRS 2.10 (1.08-4.07) 0.028 hRS 9.00 (4.61-17.56) < 0.0001 0.97 (0.64-1.48) Femoral fixation cement 0.900 non-cement

not different (p=0.734), but tRSs (p=0.030) and hRSs (p<0.0001) had higher risks. When the BPs were divided into aBPs and mBPs, with THAs as reference, aBPs had a higher risk (p=0.016) (Table 3). The following divisions of the BPs did not influence their survivorship; nBPs and oBPs, sBPs and rBPs, and hBPs and cBPs.

Survivorship illustrated with Kaplan-Meier estimator

The Kaplan-Meier estimator illustrated effects of the identified risk factors on survivorship of hip arthroplasties with need for reoperation as the endpoint. Among the ONFHassociated factor groups (Fig. 1), combined systemic steroid use and excessive alcohol consumption had a higher risk compared with the other factors; no associated factors (p=0.001), systemic steroid use (p=0.003), and excessive alcohol consumption (p=0.048). Excessive alcohol consumption was not different from no associated factors (p=0.094), nor from systemic steroid use (p=0.075). Systemic steroid use was not different from no associated factors (p=0.516). Among the surgical approaches (Fig. 2), the lateral approach was inferior to the posterior approach (p < 0.001) and to the anterior or anterolateral approach (p < 0.001). The posterior approach was not different from the anterior or anterolateral approach (p=0.085). Among the types of surgeries (Fig. 3), hRSs were inferior to the other arthroplasties (p < 0.001), and tRSs were inferior to THAs (p=0.003) and to mBPs (p=0.010) but not to aBPs (p=0.762). Alumina BPs were inferior to THAs (p=0.007) and to mBPs (p=0.008). THAs were not different from mBPs (p=0.397).

Discussion

Regarding need for reoperation, the identified risk factors were; combined systemic steroid use and excessive alcohol consumption, lateral approach, aBP, and hRS. We could not find any evidence of efficacy of the modifications made in BPs but found the deteriorating effect of the alumina outer head.

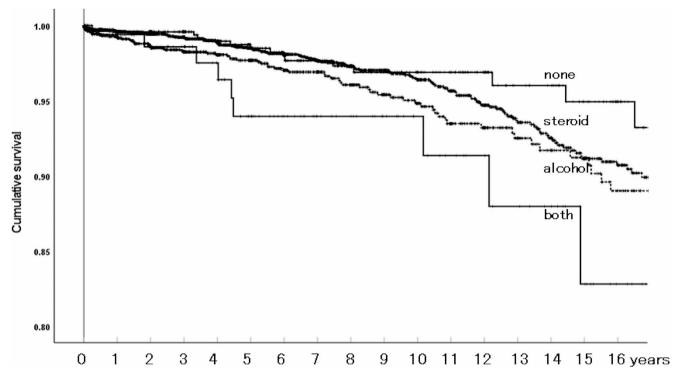


Fig. 1 Cumulative survival of hip arthroplasties among ONFH-associated factor groups with need for reoperation as the endpoint; steroid=systemic steroid use, alcohol=excessive alcohol consumption, both = combined systemic steroid use and excessive alcohol consump-

tion, and none=no associated factors. Survival rates with none, with steroid, with alcohol, and with both were 97%, 96%, 95%, and 94% at ten years, 95%, 91%, 91% and 83% at 15 years, respectively

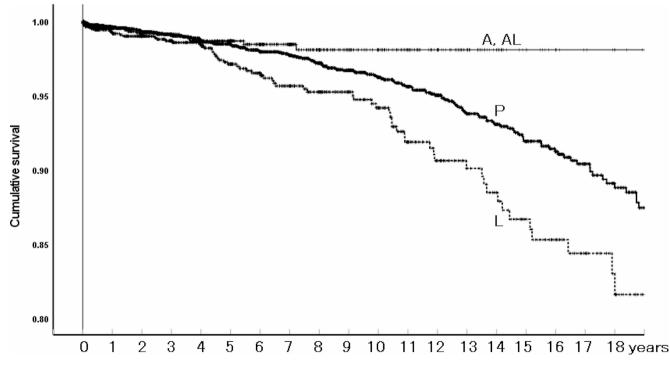


Fig. 2 Cumulative survival of hip arthroplasties among approaches (direction) with need for reoperation as the endpoint; P=posterior, A,AL=anterior or anterolateral, and L=lateral approaches. Survival

rates with A, AL, with P, and with L were 98%, 96%, and 94% at ten years, 98%, 92%, and 87% at 15 years, and 98%, 89%, and 83% at 18 years, respectively

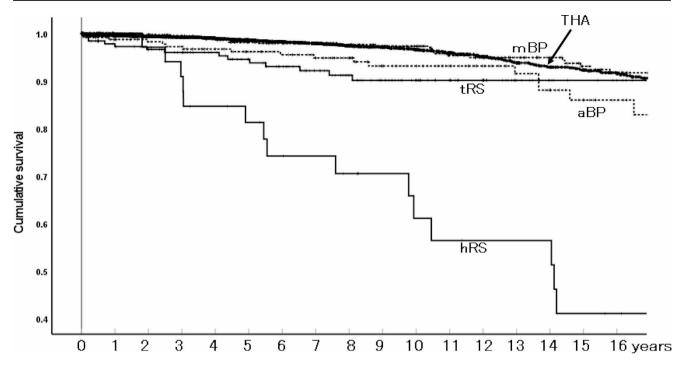


Fig. 3 Cumulative survival of hip arthroplasties among types of surgeries with need for reoperation as the endpoint. Bipolar hemiarthroplasties (BPs) were divided into two groups according to the material of the outer surface of the outer head. THA=total hip arthroplasty, aBP=BP with an alumina outer head, mBP=BP with a metal outer

Systemic steroid use and excessive alcohol consumption

Systemic steroid use [19], excessive alcohol consumption [20], and the diagnosis of ONFH itself [6, 8, 21] were risk factors associated with infection after primary THA. The infection rate of 0.77% in the present entire cohort of 7494 hip arthroplasties performed for ONFH with systemic steroid use and/or excessive alcohol consumption in 89.6% was comparable with infection rates of primary THAs mainly for OA in national registries [4, 21]. Systemic steroid use [6] and excessive alcohol consumption [22, 23] were risk factors associated with reoperation in THAs for ONFH. In the present study, combined systemic steroid use and excessive alcohol consumption was a risk factor related to need for reoperation.

Lateral approach: a risk factor for reoperation

In national register studies of THAs mainly for OA, transgluteal [24], anterior and anterolateral [25], and lateral and anterolateral [26] approaches increased revision risk due to stem loosening compared with posterior approach which possibly facilitated improved exposure for stem alignment [27]. In the present study, lateral approach was a risk factor associated with need for reoperation compared with posterior

head, tRS = total resurfacing arthroplasty, and hRS = hemi-resurfacing arthroplasty. Survival rates of THAs, mBPs, aBPs, tRSs, and hRSs were 97%, 97%, 93%, 90%, and 61% at ten years, 92% 93%, 86%, 90%, and 41% at 15 years, respectively

approach. When osteolysis, stem loosening, socket loosening, and socket and stem loosening were examined together as fixation failure (64 hips) with approach (direction), the incidence was higher with lateral approach (2.22%, 30 of 1351 hips) than with posterior approach (0.72%, 33 of 4605 hips) (χ 2 test; p < 0.001) (anterolateral, 1 hip).

Can BP be a viable treatment option for ONFH?

We could not find any evidence of efficacy of the modifications that were made to improve durability of BPs. Neither diameter, surface finish of the prosthetic neck, nor use of HXLPE in the outer head influenced survivorship of the BPs. However, we found the deteriorating effect of the alumina outer head. Poor results of 62 aBPs performed for ARCO stage III ONFH were reported, which was attributed not to the alumina outer head but to cPE in the outer head [28]. In the present study, survivorship of BPs was influenced by their division not into hBPs and cBPs but into aBPs and mBPs.

Why the aBPs were less durable? Canine studies demonstrated severe damage to acetabular cartilage in articulation with a metal femoral head [29, 30] and equally serious damage with a ceramic head [31]. Compared with unipolar hemiarthroplasty (UP), articulation with the acetabular cartilage could be reduced in BP, lowering rates of radiographic acetabular erosion and reoperation [32], but still inevitable in BP because of smaller oscillation angles built in the inner bearing (approximately 50 to 60 degrees in most BPs) than hip movements required in daily activities. In motion studies of the outer and inner bearings of BPs, the better the lubrication between the acetabulum and the outer head, the greater motion occurred at the outer bearing functioning like a UP [33, 34]. In a demographically matched study comparing 20 mBPs and 20 aBPs performed for femoral neck fracture [35], movement of the outer bearing was greater in the aBPs, which was attributed to lower friction coefficients of aBPs in articulation with acetabular cartilage than those of mBPs [36]. Therefore, the better lubrication of cartilage with aBP than with mBP could have promoted increase in motion between the acetabulum and the outer head in aBP, leading to pain, acetabular erosion, and migration of the outer head, resulting in the higher risk of reoperation in aBPs than in mBPs in the present study. As cartilage of acetabula that appeared radiographically normal before THAs performed for ONFH had already degenerated histologically [37], its articulation with the outer head could be harmful, being worse in aBPs with greater oscillating motion at the interface due to their better lubrication than in mBPs. In THAs, ceramic heads with better lubrication in a polyethylene liner provided better results than metallic heads [4]. However, in BPs, the better lubrication of ceramic heads in the acetabulum could have worked negatively raising the reoperation risk. The articulation between the acetabulum and the outer head is the fundamental problem inherent in BP. Despite the insignificant difference in survivorship between mBPs and THAs in the present study, it should be remembered that contemporary THAs with a HXLPE liner and a larger head have been reported with excellent longer-term durability and lower dislocation risk than before.

Resurfacing arthroplasties

High failure rates of hRSs, performed mainly for ONFH stage 3 hips, were shown previously [1, 38] and in the current study. In a national registry, tRS had a higher reoperation risk than THA, and tRS for ONFH had a higher revision rate than tRS for OA [4]. In the present study, tRS had a higher risk of need for reoperation compared with THA or mBP. However, the survival rate of tRS was catching up with THA and mBP after a dip within ten years (Fig. 3), which required further follow-up for conclusion.

Limitations

Prevalences of some categorical parameters might not be enough to assess their effects on the risk. Some patientrelated data were lacking, e.g., American Society of Anesthesiologists Scores studied previously [39]. Some operative data were missing. Although data on sizes of outer heads of BPs were lacking, demographic features (gender, height, weight, and BMI) were not different between aBPs and mBPs (p > 0.05). Component position [40] could not be evaluated, given the constraints involving the 31 institutions. Hip arthroplasties performed only for Japanese ONFH patients were analyzed.

Conclusions

Risk factors related to need for reoperation were combined systemic steroid use and excessive alcohol consumption, lateral approach, aBP (less durable than THAs or mBPs), and hRS. The modifications made in BPs did not improve their durability, but aBPs made it worse.

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Author contributions All authors have participated in the research.

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Data availability The data analyzed in the study are available from the corresponding author on reasonable request.

Code Availability Not applicable.

Declarations

Ethics approval Ethical approvals for this study were comprehensively obtained at three representative institutions; Shinshu University School of Medicine, Suwa Red Cross Hospital, and Osaka University Graduate School of Medicine. The procedures in this study adhered to the tenets of the Declaration of Helsinki.

Consent to participate and to publish All participants included in the study were informed and agreed to participate in this study and to have their data published in a journal.

Conflict of interest The authors declare no competing interests.

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