STROBE Statement—Checklist of items that should be included in reports of ***cohort studies***

	Item No	Recommendation	Manuscript: AO-2024-320/R2 RESUBMISSION - (18078) - Factors associated with dislocation after total hip arthroplasties performed for nontraumatic osteonecrosis of the femoral head: a multicenter cohort study of 5.,983 hips: Relevant descriptions
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title; *the study's design*: Factors associated with dislocation after THAs performed for ONFH were studied in a multicenter cohort study of 5.,983 hips
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract; *what was done*: A nationwide multicenter follow-up cohort study of THAs performed for ONFH analysed factors associated with dislocation and whether head size could reduce the dislocation risk. Abstract; *what was found*: Risk factors associated with dislocation were younger patient age, higher BMI, posterior approach, and smaller heads, however, 32-mm heads were large enough to reduce the dislocation risk.
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	*Background*: Dislocation is 1 of the 3 most common reasons for revision after THAs. Larger prosthetic heads have been used increasingly more in THAs. Larger heads have been shown to reduce the dislocation risk. However, it has not been clear how large they should be to reduce dislocation. *Rationale*: Patients with ONFH who undergo THAs are at a higher risk of postoperative dislocation. THAs performed for OFNH should be monitored, which has been conducted by the present nationwide multicenter follow-up cohort study.
Objectives	3	State specific objectives, including any prespecified hypotheses	*Objectives*: We aimed to evaluate risk factors associated with dislocation and whether larger head size could reduce the dislocation risk in patients with ONFH following a primary THA.
Methods			
Study design	4	Present key elements of study design early in the paper	***Study design*** in **Methods**: This is a prospective cohort study. Set up a nationwide multicenter follow-up cohort study of primary THAs performed for ONFH to systematically clarify patient features, operative variables, and outcomes of the

			arthroplasties including postoperative dislocation. We studied factors associated with dislocation after primary THAs performed for ONFH.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	***Setting and data source*** Hip surgeons at 31 institutions (listed in Acknowledgements) participated in the study, registering, performing hip arthroplasties on, following up the ONFH patients, and collecting the data. We studied primary THAs performed at these hospitals for ONFH or OA secondary to ONFH between January 1996 and December 2022.
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	***Study population*** Diagnosis and staging of ONFH was made according to the criteria of the committee [9]. Each ONFH patient who underwent THA was registered and followed clinically and radiographically at each institution and the follow-up status was reported to the committee every year. Criteria eligible to the study were not having a THA with very poor survivorship and ≧ 0.5-year follow-up.
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	***Variables*** Recorded demographic data were age, gender, height, weight, body mass index (BMI), ONFH-associated factors (systemic steroid use and excessive alcohol consumption), ONFH stage, and previous surgery in the index hip joint. Surgery-related data were approach, acetabular and femoral components (categorized by surface finish and use of cement in fixation), material of the acetabular articulating surface, and material and diameter of the femoral head. Follow-up information included postoperative dislocation (the outcome of the study) and the need for reoperation. *Diagnostic criteria:* ***Study population*** Diagnosis and staging of ONFH was made according to the criteria of the committee [9]. *Potential confounders and modifiers:* see Item No.9; Bias
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	***Setting and data source*** Hip surgeons at 31 institutions (listed in Acknowledgements) participated in the study, registering, performing hip arthroplasties on, following up the ONFH patients, and collecting the data. We studied primary THAs performed at these hospitals for ONFH or OA

			secondary to ONFH between January 1996 and December 2022. ***Study population*** Diagnosis and staging of ONFH was made according to the criteria of the committee [9]. Each ONFH patient who underwent THA was registered and followed clinically and radiographically at each institution and the follow-up status was reported to the committee every year.
Bias	9	Describe any efforts to address potential sources of bias	2nd paragraph in **Results**: Characteristics of the 5,983 THAs are listed in Table 1. With increasing head diameter, from 22 - 28-mm, to 32-mm, 36-mm, and 38 – 58-mm, the mean height (160.3, 161.8, 166.5, and 165.9 cm, respectively) became larger up to 36-mm ($P < 0.001$), but not between 36-mm and 38 -58-mm ($P = 0.830$). The mean weight (59.0, 61.5, 66.0, and 65.2 kg, respectively) also became larger up to 36-mm ($P < 0.001$), but not between the latter two ($P = 0.359$). The 2 groups were associated with hospitals ($P < 0.001$). Acetabular articulating material was cobalt-chrome (i.e., metal-on-metal THA) in 1.1%, 0.5%, 2.9%, and 61.6%, respectively ($P < 0.001$). ***Limitations*** in **Discussion**: Potential sources of bias have been discussed.
Study size	10	Explain how the study size was arrived at	***Study population*** in **Methods**: Diagnosis and staging of ONFH was made according to the criteria of the committee [11]. Each ONFH patient who underwent THA was registered and followed clinically and radiographically at each institution and the follow-up status was reported to the committee every year. Criteria eligible to the study were not having a THA with very poor survivorship and ≧ 0.5-year follow-up. 1st paragraph in **Results**: Dislocation risk was analyzed in 5,983 THAs (in 4,685 patients) with a median 7.1 (0.5–27)-year follow-up (94% of the originally registered cohort of 6,382 THAs), excluding 43 ABS THAs with very poor survivorship and 356 THAs with < 0.5-year follow-up that was regarded as being not long enough to assess dislocation (Figure 1). The ABS THA

			(Kyocera, Kyoto, Japan) had a thin alumina liner supported by polyethylene in a socket. In our survey, they had a very low survival rate (62% at 10 years and 55% at 15 years). The study group of 5,983 THAs was composed of 3,951 THAs with current follow-up, 1,956 THAs not with current but with ≧ 0.5-year follow-up, and 76 THAs reoperated > 0.5 year after THA (due to recurrent dislocation in 20 hips, prosthetic joint infection 14, periprosthetic femoral fracture 11, and other reasons 31 [≦ 8 for each]). Reoperation was regarded as the end of follow-up. The 3,951, 1,956, and 76 THAs were followed up for ≧ 0.5 year and were analyzed together concerning dislocation. **Figure 1**. Flowchart of selecting the study group of 5,983 primary total hip arthroplasties (THAs) from the originally registered cohort of 6,382 THAs.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	**Table 1**. Characteristics of the 5,983 THAs performed for nontraumatic osteonecrosis of the femoral head (ONFH) **Tables 2 – 7.** .Patient age was categorised into quartiles.
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	***Statistics*** in **Methods**: Risk factors were analyzed for postoperative dislocation with a multivariable logistic regression model using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA). The normality of distribution was examined with the Kolmogorov-Smirnov test. A $\chi 2$ test examined the relationship between the variables. Univariable analyses were first performed applying the model to each of the demographic and operative variables with a significance level of $P < 0.1$. Relationship between candidates with $P < 0.1$ was analyzed, and from those with strong association, one of them was deleted. A candidate that was difficult to associate with dislocation without previous reports was also excluded. The remaining candidates were then analyzed together using the model with a significance level of $P < 0.05$ (multivariable analysis). IBM SPSS statistics version 29 (IBM Corp, Armonk, NY, USA) was also

	used to perform statistics including $\chi 2$ test, t-test, one-way analysis of variance, with a significance level of $P < 0.05$. To determine the threshold of head diameter that minimized dislocation risk (the secondary objective), the Receiver Operating Characteristic (ROC) curve was plotted.
(*b*) Describe any methods used to examine subgroups and interactions	***Statistics*** in **Methods**: . . . A $\chi 2$ test examined the relationship between the variables. Univariable analyses were first performed applying the model to each of the demographic and operative variables with a significance level of $P < 0.1$. Relationship between candidates with $P < 0.1$ was analyzed, and from those with strong association, one of them was deleted. . . . IBM SPSS statistics version 29 (IBM Corp, Armonk, NY, USA) was also used to perform statistics including $\chi 2$ test, t-test, one-way analysis of variance, with a significance level of $P < 0.05$. . .
(*c*) Explain how missing data were addressed	1st paragraph in **Results**: Dislocation risk was analyzed in 5,983 THAs (in 4,685 patients) with a median 7.1 (0.5–27)-year follow-up (94% of the originally registered cohort of 6,382 THAs), excluding 43 ABS THAs with very poor survivorship and 356 THAs with < 0.5-year follow-up that was regarded as being not long enough to assess dislocation (Figure 1). The ABS THA (Kyocera, Kyoto, Japan) had a thin alumina liner supported by polyethylene in a socket. In our survey, they had a very low survival rate (62% at 10 years and 55% at 15 years). The study group of 5,983 THAs was composed of 3,951 THAs with current follow-up, 1,956 THAs not with current but with ≧ 0.5-year follow-up, and 76 THAs reoperated > 0.5 year after THA (due to recurrent dislocation in 20 hips, prosthetic joint infection 14, periprosthetic femoral fracture 11, and other reasons 31 [≦ 8 for each]). Reoperation was regarded as the end of follow-up. The 3,951, 1,956, and 76 THAs were followed up for ≧ 0.5 year and were analyzed together concerning dislocation.
(*d*) If applicable, explain how loss to follow-up was addressed	See above, Item No. 12 (c).
(*e*) Describe any sensitivity analyses	2nd paragraph in ***Risk factors for dislocation*** in **Results**:

			The multivariable analysis identified younger patient age, higher BMI, posterior approach, and smaller prosthetic heads as risk factors (Table 3). . . . The results were robust to a sensitivity analysis applied to 2,854 hips performed for stage 4 (OA) ONFH (Table 4). However, in a sensitivity analysis applied to 3,129 hips performed for stage 3 or 2 (before development of OA) ONFH, the younger patient age was not a risk factor (Table 5). To decrease influence of late dislocation, sensitivity analysis was applied to 4,509 THAs with < 10-year follow-up (median 5.3 years), resulting in the similar results except for the younger patient age and previous hip surgery (Table 6). When sensitivity analysis was performed with the study group of 5,983 THAs dividing the ≧ 36-mm group into 36-mm and 38-58-mm subgroups, both of them were not different from the 32-mm group (Table 7). . . .
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	***Study population*** Diagnosis and staging of ONFH was made according to the criteria of the committee [9]. Each ONFH patient who underwent THA was registered and followed clinically and radiographically at each institution and the follow-up status was reported to the committee every year. Criteria eligible to the study were not having a THA with very poor survivorship and ≧ 0.5-year follow-up. 1st paragraph in **Results**: Dislocation risk was analyzed in 5,983 THAs (in 4,685 patients) with a median 7.1 (0.5–27)-year follow-up (94% of the originally registered cohort of 6,382 THAs), excluding 43 ABS THAs with very poor survivorship and 356 THAs with < 0.5-year follow-up that was regarded as being not long enough to assess dislocation (Figure 1). ABS THA (Kyocera, Kyoto, Japan) had a thin alumina liner supported by polyethylene in a socket. In our survey, they had a very low survival rate (62% at 10 years and 55% at 15 years). The study group of 5,983 THAs was composed of 3,951 THAs with current follow-up, 1,956 THAs not with current but with ≧ 0.5-year follow-up, and 76 THAs reoperated > 0.5 year after THA (due to recurrent dislocation in 20 hips, prosthetic joint infection 14,

			periprosthetic femoral fracture 11, and other reasons 31 [≦ 8 for each]). Reoperation was regarded as the end of follow-up. The 3,951, 1,956, and 76 THAs were followed up for ≧ 0.5 year and were analyzed together concerning dislocation. **Figure 1**. Flowchart of selecting the study group of 5,983 primary total hip arthroplasties (THAs) from the originally registered cohort of 6,382 THAs.
		(b) Give reasons for non-participation at each stage	See above, Item No. 13 (a).
		(c) Consider use of a flow diagram	**Figure 1**. Flowchart of selecting the study group of 5,983 primary total hip arthroplasties (THAs) from the originally registered cohort of 6,382 THAs.
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	*Characteristics of study participants:* 2nd paragraph in **Results**: Characteristics of the 5,983 THAs are listed in Table 1. **Table 1**. Characteristics of the 5,983 THAs performed for nontraumatic osteonecrosis of the femoral head (ONFH) *Exposures:* ***Study population*** in **Methods**: Diagnosis and staging of ONFH was made according to the criteria of the committee [11]. Each ONFH patient who underwent THA was registered and followed clinically and radiographically at each institution and the follow-up status was reported to the committee every year. *Potential confounders:* 2nd paragraph in **Results**: Characteristics of the 5,983 THAs are listed in Table 1. With increasing head diameter, from 22–28-mm, to 32-mm, 36-mm, and 38–58-mm, the mean height (160.3, 161.8, 166.5, and 165.9 cm, respectively) became larger up to 36-mm ($P < 0.001$), but not between 36-mm and 38–58-mm ($P = 0.8$). The mean weight (59.0, 61.5, 66.0, and 65.2 kg, respectively) also became larger up to 36 mm ($P < 0.001$), but not between the latter 2 ($P = 0.4$). The 2 groups were associated with hospitals ($P < 0.001$). Acetabular articulating material was

			cobalt-chrome (i.e., metal-on-metal THA) in 1.1%, 0.5%, 2.9%, and 61.6%, respectively (P < 0.001). ***Limitations*** in **Discussion**: Potential confounders have been discussed.
		(b) Indicate number of participants with missing data for each variable of interest	1st paragraph in **Results**: Dislocation risk was analyzed in 5,983 THAs (in 4,685 patients) with a median 7.1 (0.5–27)-year follow-up (94% of the originally registered cohort of 6,382 THAs), excluding 43 ABS THAs with very poor survivorship and 356 THAs with < 0.5-year follow-up that was regarded as being not long enough to assess dislocation (Figure 1). ABS THA (Kyocera, Kyoto, Japan) had a thin alumina liner supported by polyethylene in a socket. In our survey, they had a very low survival rate (62% at 10 years and 55% at 15 years). The study group of 5,983 THAs was composed of 3,951 THAs with current follow-up, 1,956 THAs not with current but with ≧ 0.5-year follow-up, and 76 THAs reoperated > 0.5 year after THA (due to recurrent dislocation in 20 hips, prosthetic joint infection 14, periprosthetic femoral fracture 11, and other reasons 31 [≦ 8 for each]). Reoperation was regarded as the end of follow-up. The 3,951, 1,956, and 76 THAs were followed up for ≧ 0.5 year and were analyzed together concerning dislocation. 2nd paragraph in **Results**: Characteristics of the 5,983 THAs are listed in Table 1. **Table 1.** Characteristics of the 5,983 THAs performed for nontraumatic osteonecrosis of the femoral head (ONFH)
		(c) Summarise follow-up time (eg, average and total amount)	1st paragraph in **Results**: Dislocation risk was analyzed in 5,983 THAs (in 4,685 patients) with a median 7.1 (0.5–27)-year follow-up (94% of the originally registered cohort of 6,382 THAs), excluding 43 ABS THAs with very poor survivorship and 356 THAs with < 0.5-year follow-up that was regarded as being not long enough to assess dislocation (Figure 1).
Outcome data	15*	Report numbers of outcome events or summary measures over time	2nd paragraph in **Results**:

			Characteristics of the 5,983 THAs are listed in Table 1. . . . During the follow-up, 288 THAs (4.8%) dislocated. . . .
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	***Risk factors for dislocation*** in **Results**: The univariable analyses identified 8 of the variables listed in Table 1 with P < 0.1 (Table 2). Femoral component fixation, difficult to be associated with dislocation, without previous reports (to our knowledge), and having relation with 6 of the other 7 candidates, was not included in the next multivariable analyses. Femoral head material was related with 5 of the other 6 candidates. Its relationship with dislocation could not be found in the literature, although hard-on-hard bearing was reported regarding dislocation, which was analyzed with acetabular articulating material. Therefore, femoral head material was not included either. As the remaining 6 variables had been reported concerning dislocation, and without strong relationship between them, they were examined together with the model. The multivariable analysis identified younger patient age, higher BMI, posterior approach, and smaller prosthetic heads as risk factors (Table 3). . . . The results were robust to a sensitivity analysis applied to 2,854 hips performed for stage 4 (OA) ONFH (Table 4). However, in a sensitivity analysis applied to 3,129 hips performed for stage 3 or 2 (before development of OA) ONFH, the younger patient age was not a risk factor (Table 5). To decrease influence of late dislocation, sensitivity analysis was applied to 4,509 THAs with < 10-year follow-up (median 5.3 years), resulting in the similar results except for the younger patient age and previous hip surgery (Table 6). When sensitivity analysis was performed with the study group of 5,983 THAs dividing the ≧ 36-mm group into 36-mm and 38-58-mm subgroups, both of them were not different from the 32-mm group (Table 7). . . . **Tables 2 – 7.**
		(*b*) Report category boundaries when continuous variables were categorized	**Tables 2 – 7.** Patient age was categorised into quartiles.
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	***Strengths*** in **Discussion**: Demographic, surgical, and follow-up status information could be obtained precisely because of the prospective nature of the study, and the incidence rate of dislocation (which could be difficult to detect accurately in national registries) reflects the true value.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	*Sensitivity analyses:* 2nd paragraph in ***Risk factors for dislocation*** in **Results**: The multivariable analysis identified younger patient age, higher BMI, posterior

approach, and smaller prosthetic heads as risk factors (Table 3). . . . The results were robust to a sensitivity analysis applied to 2,854 hips performed for stage 4 (OA) ONFH (Table 4). However, in a sensitivity analysis applied to 3,129 hips performed for stage 3 or 2 (before development of OA) ONFH, the younger patient age was not a risk factor (Table 5). To decrease influence of late dislocation, sensitivity analysis was applied to 4,509 THAs with < 10-year follow-up (median 5.3 years), resulting in the similar results except for the younger patient age and previous hip surgery (Table 6). When sensitivity analysis was performed with the study group of 5,983 THAs dividing the ≧ 36-mm group into 36-mm and 38-58-mm subgroups, both of them were not different from the 32-mm group (Table 7). . . .

Receiver Operating Characteristic (ROC) curve:

Statistics in **Methods**:

. . . To determine the threshold of head diameter that minimized dislocation risk (the secondary objective), the Receiver Operating Characteristic (ROC) curve was plotted.

2nd paragraph in ***Risk factors for dislocation*** in **Results**:

. . . On the ROC curve plotted to determine the threshold of head diameter that minimized dislocation risk, the point closest to the (0, 1) point was 30 mm in head diameter (Figure 2).

Figure 2. Receiver Operating Characteristic (ROC) curve plotting the true positive rate (sensitivity) against the false positive rate (1 – specificity) representing the portion of THAs with dislocation against without regarding head diameter which was treated as a continuous variable. On the curve, the point closest to the (0, 1) point is 30 mm in head diameter with sensitivity of 0.68 and 1-specificity of 0.42 (arrow), which could be the threshold indicating ≧ 32-mm heads could reduce the dislocation risk. Area under ROC curve is 0.65 (95% confidence interval, 0.62 – 0.69).

Discussion			
Key results	18	Summarise key results with reference to study objectives	1st paragraph in **Discussion**: This is the largest prospective follow-up cohort study of primary THAs performed for ONFH. We aimed to evaluate risk factors associated with dislocation and whether larger head size could reduce the dislocation risk in patients with ONFH following a primary THA. In this nationwide study we show the following risk factors associated with postoperative dislocation; younger (≦ 41 years) patient age, higher BMI, posterior approach, and smaller prosthetic heads. Although larger heads were less likely to dislocate, 32-mm heads were large enough to reduce dislocation.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	***Limitations*** in **Discussion**: Potential bias and confounders have been discussed.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Identified risk factors were discussed with reference to previous studies in the following sessions: ***Patient age as a risk factor changed with time, and obesity***, ***Recently mitigated dislocation risk with posterior approach***, ***32-mm heads were large enough to reduce dislocation***, ***Strengths***, and ***Limitations***.
Generalisability	21	Discuss the generalisability (external validity) of the study results	***32-mm heads were large enough to reduce dislocation*** in **Discussion**: . . . In the present study, primary THAs performed only in Japanese ONFH patients were analyzed, the results of which require further research for external validity. ***Limitations*** in **Discussion**: Potential bias and confounders have been discussed.
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	***Ethics, data sharing plan, use of AI, funding, and potential conflicts of interest*** in **Methods**: . . . This study was supported by a research grant from the Health Labour Sciences Research Grant, the Ministry of Health, Labour and Welfare, Japan (23FC0201). Except for the funding, the authors received or will receive no financial or material support for the research, authorship, and/or publication

	of this article. Complete disclosure of interest forms according to ICMJE are available on the article page, doi:

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.