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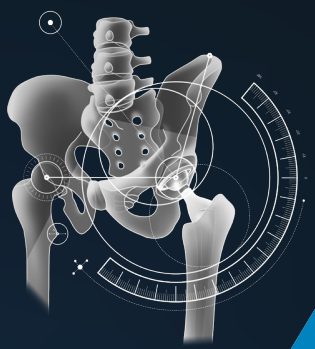

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A Prospective, Longitudinal Study of the Influence of Obesity on Total Knee Arthroplasty Revision Rate

Results from the Australian Orthopaedic Association National Joint Replacement Registry

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Investigation performed at the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), Adelaide, South Australia, Australia, and the South Australian Health and Medical Research Institute (SAHMRI), Adelaide, South Australia, Australia

Background: The aim of this study was to investigate the relationship of obesity with all-cause revision and revision for infection, loosening, instability, and pain after total knee arthroplasty (TKA) performed in Australia.

Methods: Data for patients undergoing primary TKA for osteoarthritis from January 1, 2015, to December 31, 2020, were obtained from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The rates of all-cause revision and revision for infection, loosening, instability, and pain were compared for non-obese patients (body mass index [BMI], 18.50 to 29.99 kg/m^2), class-I and II obese patients (BMI, 30.00 to 39.99 kg/m^2), and class-III obese patients (BMI, ≥40.00 kg/m^2). The results were adjusted for age, sex, tibial fixation, prosthesis stability, patellar component usage, and computer navigation usage.

Results: During the study period, 141,673 patients underwent primary TKA for osteoarthritis in Australia; of these patients, 48.0% were class-I or II obese, and 10.6% were class-III obese. The mean age was 68.2 years, and 54.7% of patients were female. The mean follow-up period was 2.8 years. Of the 2,655 revision procedures identified, the reasons for the procedures included infection in 39.7%, loosening in 14.8%, instability in 12.0%, and pain in 6.1%. Class-I and II obese patients had a higher risk of all-cause revision (hazard ratio [HR], 1.12 [95% confidence interval (CI), 1.03 to 1.22]; p = 0.007) and revision for infection (HR, 1.25 [95% CI, 1.10 to 1.43]; p = 0.001) than non-obese patients. Class-III obese patients had a higher risk of all-cause revision after 1 year (HR, 1.30 [95% CI, 1.14 to 1.52]; p < 0.001), revision for infection after 3 months (HR, 1.72 [95% CI, 1.33 to 2.17]; p < 0.001), and revision for loosening (HR, 1.39 [95% CI, 1.00 to 1.89]; p = 0.047) than non-obese patients. The risks of revision for instability and pain were similar among groups.

Conclusions: Obese patients with knee osteoarthritis should be counseled with regard to the increased risks associated with TKA, so they can make informed decisions about their health care. Health services and policymakers need to address the issue of obesity at a population level.

Level of Evidence: Prognostic Level III. See Instructions for Authors for a complete description of levels of evidence.

Knee osteoarthritis is a common cause of pain and disability that is increasing in prevalence globally[1,2]. Total knee arthroplasty (TKA) is a reliable and cost-effective treatment option for patients with severe knee osteoarthritis who exhaust conservative management[3,4]. Obesity is a known risk factor for the development of knee osteoarthritis and is also associated with an increased risk of undergoing TKA[5-7]. The global prevalence of obesity has increased dramatically since 1975[8]. In Australia, 31% of adults are obese[9], and 59% of patients undergoing TKA are obese[10].

Although obese patients with knee osteoarthritis generally experience satisfactory outcomes following TKA, there is growing concern about the risk of adverse outcomes in this cohort of patients[11,12]. Some recent systematic reviews and meta-analyses have demonstrated that obese patients, and particularly morbidly obese patients, have a higher risk of perioperative complications following TKA, including all-cause revision and revision for infection[13-15]. The association between obesity and aseptic revision is less clearly defined, with conflicting results in the literature[16-21].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H91).

The aim of this study was to investigate the relationship of obesity with all-cause revision and revision for infection, loosening, instability, and pain following TKA, using data from a large, national joint replacement registry.

Materials and Methods

On September 1, 1999, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) began collecting data, and national implementation was completed by 2002. Since then, the AOANJRR has collected data on almost 100% of TKAs performed in Australia. The AOANJRR has collected body mass index (BMI) data for all TKAs performed since 2015. Patients are categorized by BMI according to the World Health Organization (WHO) classification[22].

AOANJRR data are externally validated against patient-level data provided by all Australian state and territory health departments[10]. A sequential, multilevel matching process is used to identify any missing data, which are subsequently retrieved by contacting the relevant hospital. Each month, in conjunction with internal validation and data quality checks, all primary procedures are linked to any subsequent revision involving the same patient, same joint, and same side. Data are also matched biannually with the Australian Government's National Death Index to obtain information on the date of death. Linking revision and death to the primary procedure enables revision rates to be determined[23].

Data from the AOANJRR were obtained for TKAs performed as the primary procedure for a diagnosis of osteoarthritis from January 1, 2015, to December 31, 2020. Patients who underwent a revision procedure during the study period were identified. Revision was defined as removal, replacement, or addition of any device component. The cumulative percent revision (CPR) was calculated for all-cause revision and revision for infection, loosening, instability, and pain. The CPR was compared for non-obese patients (BMI, 18.50 to 29.99 kg/m^2), class-I and II obese patients (BMI, 30.00 to 39.99 kg/m^2), and class-III obese patients (BMI, ≥40.00 kg/m^2) for each revision diagnosis. Underweight patients (BMI, <18.50 kg/m^2) were excluded from the study, as were TKAs performed with non-cross-linked polyethylene, due to a previous AOANJRR report of higher infection risk with non-cross-linked polyethylene[24].

The Kaplan-Meier method was used to calculate estimates of the CPR. The end point was the time interval to the first revision for any cause. Unadjusted CPRs are reported with 95% confidence intervals (CIs). Hazard ratios (HRs) calculated from Cox proportional hazards models were used to compare revision rates. A multivariable model was fitted to the data. HRs were adjusted for age, sex, tibial fixation, prosthesis stability

TABLE I Demographic Data for Patients Who Underwent Primary TKA for Osteoarthritis in Australia During the Study Period

	BMI Category*			
	Non-Obese (N = 58,656)	Obese Classes I and II (N = 68,007)	Obese Class III (N = 15,010)	Total (N = 141,673)
Age				
Mean† *(yr)*	70.3 ± 8.9	67.4 ± 8.5	64 ± 8.1	68.2 ± 8.9
<55 years†	2,382 (4.1%)	4,666 (6.9%)	1,887 (12.6%)	8,935 (6.3%)
55 to 64 years†	12,697 (21.6%)	19,891 (29.2%)	5,950 (39.6%)	38,538 (27.2%)
65 to 74 years†	23,768 (40.5%)	29,441 (43.3%)	5,710 (38.0%)	58,919 (41.6%)
≥75 years†	19,809 (33.8%)	14,009 (20.6%)	1,463 (9.7%)	35,281 (24.9%)
Sex†				
Male	29,393 (50.1%)	30,608 (45.0%)	4,190 (27.9%)	64,191 (45.3%)
Female	29,263 (49.9%)	37,399 (55.0%)	10,820 (72.1%)	77,482 (54.7%)
ASA score†§				
1	5,088 (8.7%)	2,403 (3.5%)	94 (0.6%)	7,585 (5.4%)
2	36,188 (61.8%)	36,852 (54.3%)	3,852 (25.7%)	76,892 (54.4%)
3	16,879 (28.8%)	28,029 (41.3%)	10,620 (70.9%)	55,528 (39.3%)
4	380 (0.6%)	607 (0.9%)	422 (2.8%)	1,409 (1.0%)
5	2 (0.01%)	2 (0.01%)	0 (0%)	4 (0.01%)
Hospital type†				
Private hospital	42,838 (73.0%)	44,703 (65.7%)	8,727 (58.1%)	96,268 (68.0%)
Public hospital	15,818 (27.0%)	23,304 (34.3%)	6,283 (41.9%)	45,405 (32.0%)
Follow-up† *(yr)*	2.8 ± 1.7	2.8 ± 1.7	2.8 ± 1.6	2.8 ± 1.7

*The BMI categories were non-obese (BMI, 18.50 to 29.99 kg/m^2), obese classes I and II (BMI, 30.00 to 39.99 kg/m^2), and obese class III (BMI, ≥40.00 kg/m^2). †The values are given as the mean and the standard deviation. ‡The values are given as the number of patients, with the percentage in parentheses. §This category excludes 255 patients who had an unknown ASA score.

TABLE II The Number of TKAs at Risk for Revision, by BMI Category and Minimum Duration of Follow-up

BMI Category*	Minimum Duration of Follow-up†					
	0 Years	1 Year	2 Years	3 Years	4 Years	5 Years
Non-obese	58,656	48,177	37,359	26,639	16,579	7,462
Obese classes I and II	68,007	56,200	43,480	30,751	18,850	8,280
Obese class III	15,010	12,557	9,780	6,942	4,259	1,834

*The BMI categories were non-obese (BMI, 18.50 to 29.99 kg/m^2), obese classes I and II (BMI, 30.00 to 39.99 kg/m^2), and obese class III (BMI, ≥40.00 kg/m^2). †The values are given as the number of patients.

(minimally stabilized, medial pivot design, and posterior stabilized), patellar component usage, and computer navigation usage, as each of these variables has been shown to influence revision rate in the AOANJRR[10]. Although the AOANJRR collects American Society of Anesthesiologists (ASA) scores, these were not included in the risk adjustment, as the ASA score is directly influenced by BMI[25]. The assumption of proportional hazards was checked by testing for a significant interaction between each covariate and the log of time. Statistical analysis was performed using SAS version 9.4 (SAS Institute). Significance was set at $p < 0.05$.

The AOANJRR is approved by the Commonwealth of Australia as a Federal Quality Assurance Activity under Part VC of the Health Insurance Act, 1973. All AOANJRR studies are conducted in accordance with ethical principles of research (Helsinki Declaration II).

Source of Funding

The AOANJRR is funded by the Commonwealth of Australia Department of Health. No other sources of funding were used in this study.

Results

During the study period, 141,673 patients with recorded BMI underwent primary TKA for osteoarthritis in Australia. Of these patients, 54.7% were female, and the mean age was 68.2 years. Forty-eight percent of patients were class-I or II obese, and 10.6% were class-III obese. The mean follow-up period was 2.8 years. Demographic data are provided in Table I. The total number of TKAs at risk for revision, by BMI category and minimum duration of follow-up, is presented in Table II.

There were 2,655 patients (1.9%) who underwent a revision procedure during the study period. Demographic data for these patients are presented in Table III. Of the revision procedures, 1,055 (39.7%) were performed for infection, 392 (14.8%) were performed for loosening, 318 (12.0%) were performed for instability, 163 (6.1%) were performed for pain, and 727 (27.4%) were performed for other reasons (e.g., patellofemoral pain, patellar erosion, arthrofibrosis, fracture, malalignment[10]), and there was no further analysis performed for the "other" group.

There was a significant difference in all-cause revision among the 3 patient groups (Fig. 1). At 5 years postoperatively, the all-cause CPR was 2.5% (95% CI, 2.3% to 2.6%) for non-obese patients, 2.9% (95% CI, 2.7% to 3.0%) for class-I and II obese patients, and 3.3% (95% CI, 2.9% to 3.7%) for class-III obese patients. Comparing class-III obese patients with non-obese patients, the HR varied with time, but was significant for all time periods chosen. The HR was 1.30 (95% CI, 1.14 to 1.52; $p < 0.001$) after 1 year postoperatively (Table IV). Comparing class-I and II obese patients with non-obese patients, the HR was 1.12 (95% CI, 1.03 to 1.22; $p = 0.007$). Comparing class-III obese patients with class-I and II obese patients, the HR was 1.18 (95% CI, 1.04 to 1.33; $p = 0.006$).

There was also a significant difference in revision for infection among patient groups (Fig. 2). At 5 years postoperatively, the CPR for infection was 0.8% (95% CI, 0.7% to 0.9%)

TABLE III Demographic Data for Patients Who Underwent a Revision Procedure During the Study Period

	BMI Category*			
	Non-Obese (N = 971)	Obese Classes I and II (N = 1,325)	Obese Class III (N = 359)	Total (N = 2,655)
Age† *(yr)*	67.9 ± 9.5	65.4 ± 9	62.5 ± 8.2	65.9 ± 9.3
Sex‡				
Male	542 (55.8%)	721 (54.4%)	142 (39.6%)	1,405 (52.9%)
Female	429 (44.2%)	604 (45.6%)	217 (60.4%)	1,250 (47.1%)

*The BMI categories were non-obese (BMI, 18.50 to 29.99 kg/m^2), obese classes I and II (BMI, 30.00 to 39.99 kg/m^2), and obese class III (BMI, ≥40.00 kg/m^2). †The values are given as the mean and the standard deviation. ‡The values are given the number of patients, with the percentage in parentheses.

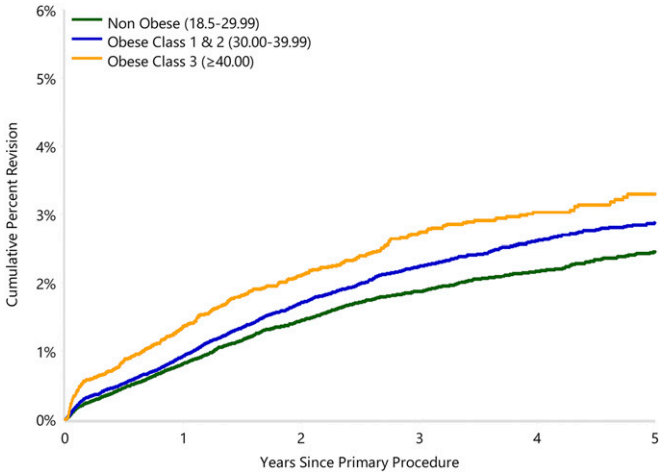

Fig. 1

The CPR of primary TKA for osteoarthritis by BMI category: all-cause revision.

for non-obese patients, 1.0% (95% CI, 0.9% to 1.1%) for class-I and II obese patients, and 1.4% (95% CI, 1.2% to 1.7%) for class-III obese patients. Comparing class-III obese patients with non-obese patients, the HR varied with time, but was significant for all time periods chosen. The HR was 2.86 (95% CI, 2.13 to 3.85; $p < 0.001$) from 0 to 3 months postoperatively and 1.72 (95% CI, 1.33 to 2.17; $p < 0.001$) thereafter (Table IV). Comparing class-I and II obese patients with non-obese patients, the HR was 1.25 (95% CI, 1.10 to 1.43; $p = 0.001$). Comparing class-III obese patients with class-I and II obese patients, the HR varied with time, but was significant for all time periods chosen. The HR was 2.04 (95% CI, 1.56 to 2.70; $p < 0.001$) from 0 to 3 months postoperatively and 1.45 (95% CI, 1.15 to 1.82; $p = 0.001$) thereafter.

Class-III obese patients had a higher risk of revision for loosening than non-obese patients, but there was no difference among other groups (Fig. 3). At 5 years postoperatively, the CPR for loosening was 0.3% (95% CI, 0.3% to 0.4%) for non-obese patients, 0.5% (95% CI, 0.5% to 0.6%) for class-I and II obese patients, and 0.6% (95% CI, 0.5% to 0.8%) for class-III obese patients. Comparing class-III obese patients with non-obese patients, the HR was 1.39 (95% CI, 1.00 to 1.89; $p = 0.047$) (Table IV).

There was no difference in risk of revision for instability or pain among patient groups (Table IV).

Discussion

The most clinically important finding of this study is that obese patients have a higher risk of all-cause revision and revision for infection following TKA than non-obese patients. Patients with class-III, or morbid, obesity also have a higher risk of revision for loosening compared with non-obese patients.

These findings complement other studies and give greater credence to the challenge of performing TKA in obese patients. In a systematic review and meta-analysis, Kerkhoffs et al. demonstrated an increased risk of all-cause revision in obese patients (BMI ≥30 kg/m^2) compared with non-obese patients (BMI, <30 kg/m^2) (odds ratio, 1.30 [95% CI, 1.02 to 1.67])[15]. In a systematic review, Boyce et al. found a higher risk of all-cause revision for morbidly obese patients (BMI, ≥40 kg/m^2) compared with non-obese patients (BMI, ≤30 kg/m^2), with mean revision rates of 7% for morbidly obese patients and 2% for non-obese patients ($p < 0.001$)[14]. In a systematic review and meta-analysis, Chaudhry et al.[13] demonstrated increased risks of all-cause revision for patients with severe obesity (BMI of ≥35 kg/m^2:

TABLE IV Risk of Revision Following Primary TKA for Osteoarthritis by BMI Category and Revision Diagnosis*

	Obese Class III Compared with Non-Obese		Obese Classes I and II Compared with Non-Obese		Obese Class III Compared with Obese Classes I and II	
Revision Diagnosis	HR†	P Value	HR†	P Value	HR†	P Value
All-cause			1.12 (1.03 to 1.22)	0.007‡	1.18 (1.04 to 1.33)	0.006‡
0 to 3 months	1.54 (1.16 to 2.04)	0.002‡				
3 months to 1 year	1.28 (1.10 to 1.52)	0.002‡				
>1 year	1.30 (1.14 to 1.52)	<0.001‡				
Infection			1.25 (1.10 to 1.43)	0.001‡		
0 to 3 months	2.86 (2.13 to 3.85)	<0.001‡			2.04 (1.56 to 2.70)	<0.001‡
>3 months	1.72 (1.33 to 2.17)	<0.001‡			1.45 (1.15 to 1.82)	0.001‡
Loosening	1.39 (1.00 to 1.89)	0.047‡	1.23 (0.99 to 1.54)	0.063	1.11 (0.83 to 1.49)	0.460
Instability	1.00 (0.67 to 1.47)	0.981	1.25 (0.98 to 1.59)	0.073	0.80 (0.55 to 1.15)	0.227
Pain	0.56 (0.31 to 1.04)	0.066	0.94 (0.68 to 1.30)	0.710	0.60 (0.33 to 1.09)	0.091

*The BMI categories were non-obese (BMI, 18.50 to 29.99 kg/m^2), obese classes I and II (BMI, 30.00 to 39.99 kg/m^2), and obese class III (BMI, ≥40.00 kg/m^2). †The values are given as the HR, with the 95% CI in parentheses. The HRs were adjusted for age, sex, tibial fixation, prosthesis stability (minimally stabilized, medial pivot design, and posterior stabilized), patellar component usage, and computer navigation usage and were presented for the entire period unless specified otherwise. ‡Significant.

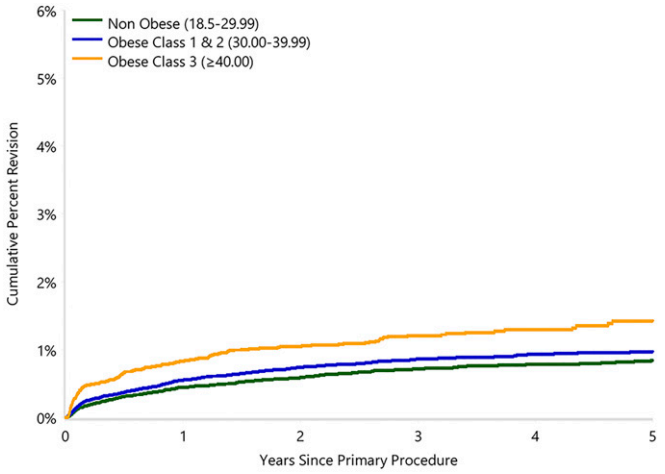

Fig. 2

The CPR of primary TKA for osteoarthritis by BMI category: revision for infection.

risk ratio, 1.19 [95% CI, 1.03 to 1.37]; p = 0.02), morbid obesity (BMI of ≥40 kg/m^2: risk ratio, 1.93 [95% CI, 1.27 to 2.95]; p < 0.001), and super obesity (BMI of ≥50 kg/m^2: risk ratio, 4.75 [95% CI, 2.12 to 10.66]; p < 0.001), compared with patients with normal BMI of <25 kg/m^2.

When comparing our results with those from other large arthroplasty registries, recently published studies from the Swedish Knee Arthroplasty Register[26] and the Catalan Arthroplasty Register[27] have shown an increased risk of all-cause revision in obese patients undergoing TKA compared with non-obese patients, whereas studies from the Dutch Arthroplasty Register[20] and the Registro Implantologia Protesica Ortopedica (RIPO)[18] in Italy have demonstrated no difference in risk between these groups.

With regard to revision for infection, our findings also align with those in previous literature. In their meta-analysis, Chaudhry et al. demonstrated an increased risk of revision for infection for patients with severe obesity (risk ratio, 1.49 [95% CI, 1.28 to 1.72]; p < 0.001), morbid obesity (risk ratio, 3.69 [95% CI, 1.90 to 7.17]; p < 0.001), and super obesity (risk ratio, 4.58 [95% CI, 1.11 to 18.91]; p < 0.001), compared with patients with a normal BMI[13].

There is some discrepancy in the effect of obesity on revision for infection among arthroplasty registries. Our study demonstrated similar findings to those in studies from the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man[28], the Swedish Knee Arthroplasty Register[26], and the Dutch Arthroplasty Register[20], whereas studies from RIPO[18] and the New Zealand Joint Registry (NZJR)[29] showed no difference in risk between obese and non-obese patients. It may be that the patient cohorts in the latter 2 studies were too small to detect a difference. Moreover, the NZJR does not record debridement with liner exchange as a revision procedure[29].

There is comparatively less literature published concerning the risk of aseptic revision in obese patients undergoing TKA. In a study from the Mayo Clinic, Wagner et al. found a higher risk of revision for any mechanical failure, specifically aseptic loosening and polyethylene wear, but no difference for component fracture or tibiofemoral instability, for obese patients undergoing TKA compared with non-obese patients[17]. In a study from the same institution, Abdel et al. noted a higher risk of revision for aseptic tibial loosening in patients with a BMI of ≥35 kg/m^2 compared with those with a BMI of <35 kg/m^2 (HR, 1.9 [95% CI, 1.0 to 3.4]; p = 0.042)[16]. In contrast, studies from the Swedish Knee Arthroplasty Register[26], the Dutch Arthroplasty Register[20], and RIPO[18] and a multicenter French study[19] did not show a significant difference in risk of aseptic revision between obese and non-obese patients undergoing TKA. Analyzing data from the Kaiser Permanente database, Namba et al. found that patients with a BMI of ≥35 kg/m^2 had a lower risk of aseptic revision than non-obese patients (BMI of <30 kg/m^2) (HR, 0.78 [95% CI, 0.63 to 0.96]; p = 0.020)[21]. They conceded that their median follow-up of 2.9 years may have been too short to detect failures due to obesity, but postulated that morbidly obese patients may be less active than non-obese patients, therefore placing less demand on their TKA[21]. In their meta-analysis, Chaudhry et al. found no significant difference in the risk of aseptic revision for patients with severe, morbid, or super obesity compared with patients with normal BMI[13].

The global prevalence of knee osteoarthritis is increasing[2], as is the utilization of TKA[10,30,31], in part driven by the increasing incidence of obesity[32,33]. Projection studies have suggested that the incidence of TKA will continue to increase[30,31,34,35], as will the burden of revision arthroplasty[31]. The findings of this study add weight to concerns about obesity as a public health issue[36].

Our study has several strengths. The AOANJRR records data for nearly 100% of TKAs performed in Australia, and loss to follow-up is negligible. We are therefore confident in the accuracy and representativeness of our findings. By using

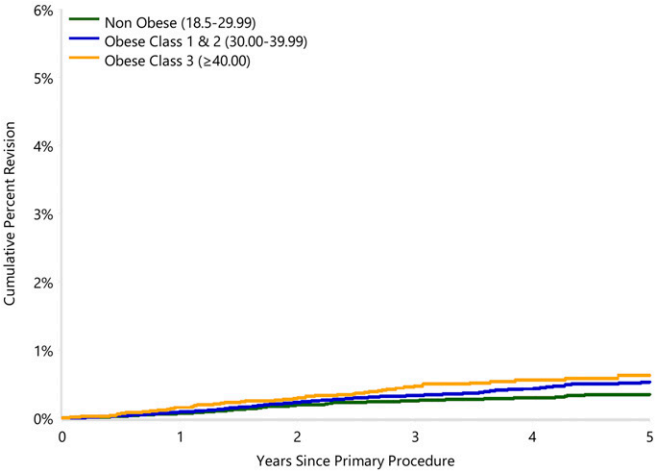

Fig. 3

The CPR of primary TKA for osteoarthritis by BMI category: revision for loosening.

national registry data, our patient cohort is large enough to detect differences in revision rates for less common revision diagnoses.

We also acknowledge that there were a number of limitations to our study. First, the AOANJRR records revision surgery as the primary outcome following TKA. We were therefore unable to comment on surgical complications and reoperations not involving the removal or addition of an implant and therefore may have underestimated the true rate of infection for patients undergoing TKA. Other outcomes such as length of stay, health-care costs, and medical complications are not routinely recorded by the registry. Second, at the time of this writing, we were unable to comment on patient-reported outcome measures for obese patients undergoing TKA. The AOANJRR has recently completed a patient-reported outcome measures pilot project and is now in the process of national implementation. We plan to publish these data in the future. Third, as our mean follow-up was 2.8 years, we were unable to comment on the longer-term revision risk for obese patients undergoing TKA. Fourth, we were unable to comment on the potential confounding role of type-2 diabetes mellitus and other comorbidities on the results of our study. Obesity and type-2 diabetes often coexist, and type-2 diabetes is known to be a risk factor for deep infection following primary TKA[37]. Unfortunately, the AOANJRR does not collect data on type-2 diabetes. Finally, tibial component malalignment has been shown to increase the risk of TKA failure in obese patients[38]. The registry does not collect preoperative or postoperative radiographic data, so we were unable to comment on the potential influence of implant malalignment on our results.

In conclusion, obese patients undergoing primary TKA for osteoarthritis have a higher risk of all-cause revision and revision for infection than non-obese patients. Class-III obese patients have a higher risk of revision for loosening than non-obese patients. The risks of revision for instability and pain are similar for obese and non-obese patients.

We believe that our findings will assist clinicians in counseling obese patients with regard to the risks associated with TKA, so that patients can make well-informed decisions about their health care. A population-level approach to address the increasing prevalence of obesity is urgently needed to reduce the burden of obesity-related knee osteoarthritis, primary TKA, and revision TKA. ■

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A commentary by Gregory J. Schmeling, MD, is linked to the online version of this article.

Radiographic Predictors of Conversion to Total Knee Arthroplasty After Tibial Plateau Fracture Surgery

Results in a Large Multicenter Cohort

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Background: Radiographic measurements of initial displacement of tibial plateau fractures and of postoperative reduction are used to determine treatment strategy and prognosis. We assessed the association between radiographic measurements and the risk of conversion to total knee arthroplasty (TKA) at the time of follow-up.

Methods: A total of 862 patients surgically treated for tibial plateau fractures between 2003 and 2018 were eligible for this multicenter cross-sectional study. Patients were approached for follow-up, and 477 (55%) responded. The initial gap and step-off were measured on the preoperative computed tomography (CT) scans of the responders. Condylar widening, residual incongruity, and coronal and sagittal alignment were measured on postoperative radiographs. Critical cutoff values for gap and step-off were determined using receiver operating characteristic curves. Postoperative reduction measurements were categorized as adequate or inadequate on the basis of cutoff values in international guidelines. Multivariable analysis was performed to assess the association between each radiographic measurement and conversion to TKA.

Results: Sixty-seven (14%) of the patients had conversion to TKA after a mean follow-up of 6.5 ± 4.1 years. Assessment of the preoperative CT scans revealed that a gap of >8.5 mm (hazard ratio [HR] = 2.6, $p < 0.001$) and step-off of >6.0 mm (HR = 3.0, $p < 0.001$) were independently associated with conversion to TKA. Assessment of the postoperative radiographs demonstrated that residual incongruity of 2 to 4 mm was not associated with increased risk of TKA compared with adequate fracture reduction of <2 mm (HR = 0.6, $p = 0.176$). Articular incongruity of >4 mm resulted in increased risk of TKA. Coronal (HR = 1.6, $p = 0.05$) and sagittal malalignment (HR = 3.7 $p < 0.001$) of the tibia were strongly associated with conversion to TKA.

Conclusions: Substantial preoperative fracture displacement was a strong predictor of conversion to TKA. Postoperative gaps or step-offs of >4 mm as well as inadequate alignment of the tibia were strongly associated with an increased risk of TKA.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

The main goals of surgery for a tibial plateau fracture are to reestablish joint stability, achieve normal limb alignment, and restore the articular surface[1,2]. Achieving these surgical goals reduces the risk of posttraumatic osteoarthritis and the subsequent need for total knee arthroplasty (TKA)[3]. However, adequate reduction is not always possible because of comminution and severe fracture displacement. A suboptimal operative result has been reported in up to 30% of surgically treated tibial plateau fractures[4]. Also, the initial irreversible damage to the articular surface may induce posttraumatic osteoarthritis despite a good operative result[5,6]. Therefore, pre- and postoperative radiographic assessments of fracture displacement

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H525).

and tibial alignment are important to estimate risks of conversion to TKA at follow-up.

Adequate preoperative assessment of fractures is essential to determine the treatment strategy and counsel patients regarding the prognosis. Initial fracture displacement, which can be assessed by measuring the intra-articular gap and step-off on preoperative computed tomography (CT) scans, is among the decisive factors in the choice between nonoperative and operative management. The results of surgical treatment are usually assessed on postoperative radiographs by measuring the quality of the reduction and tibial alignment. Since these radiographic measurements are important for both treatment decisions and patient counseling about prognosis, it is important to understand their relationship with the clinical outcome. Even though existing research suggests that initial fracture displacement, quality of reduction, and postoperative tibial alignment contribute to the development of posttraumatic osteoarthritis and the need for TKA, the actual impact of these parameters has not yet been clarified[3,6,7].

We hypothesized that initial fracture displacement, quality of reduction, and postoperative tibial alignment are predictors of conversion to TKA. The aim of this study was to answer the following research questions: (1) What is the association between the preoperative fracture displacement, in terms of gap and step-off as measured on CT scans, and the risk of conversion to TKA at the time of follow-up? (2) What is the association between the postoperative fracture reduction and knee alignment, as measured on radiographs, and the risk of conversion to TKA at the time of follow-up?

Materials and Methods

Study Design

All patients who underwent tibial plateau fracture surgery between 2003 and 2018 in 4 trauma centers (2 level-1, 2 level-2) were eligible for this retrospective multicenter cross-sectional study if they had a preoperative CT scan, postoperative anteroposterior and lateral radiographs, and follow-up of >1 year. Patients who required amputation, were <18 years old, were deceased, or had an unknown address were excluded. The baseline characteristics of the included patients were retrieved from the electronic patient file. Patients were approached by mail and asked whether they still had their own, native knee (without conversion to TKA) and whether they had undergone

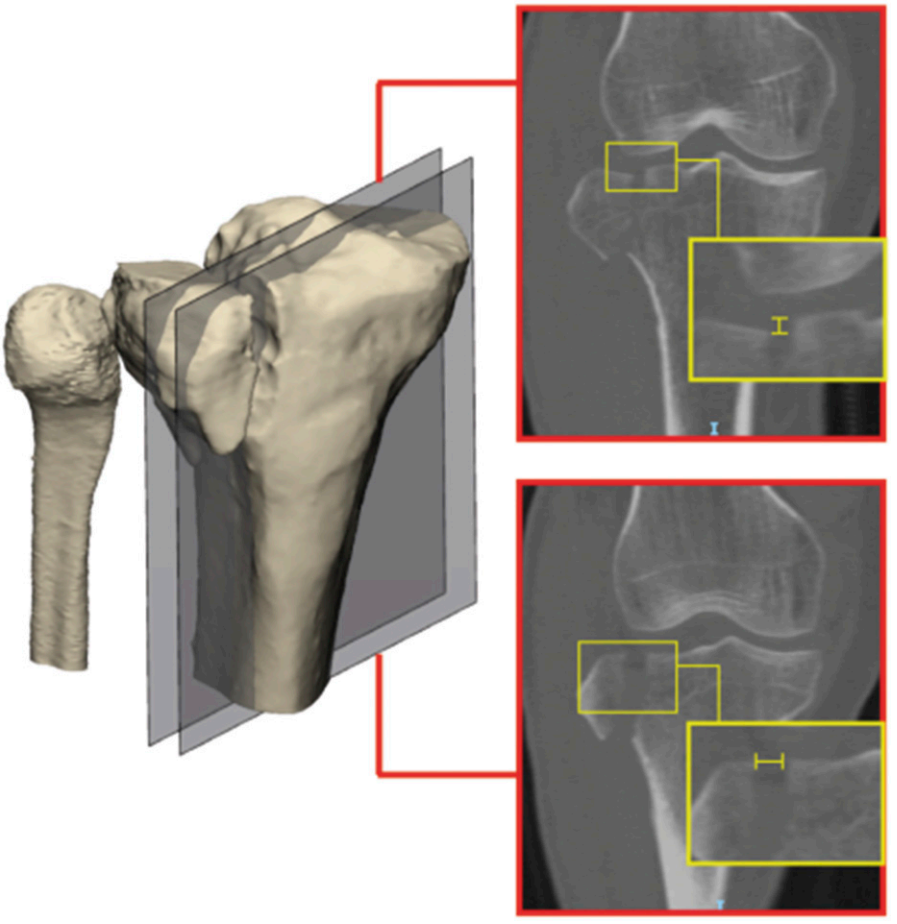

Fig. 1

Gap and step-off measurements performed on separate coronal slices. *Upper right:* step-off measurement, defined as the separation of fracture fragments perpendicular to the articular surface. *Lower right:* gap measurement, defined as the separation of fracture fragments along the articular surface.

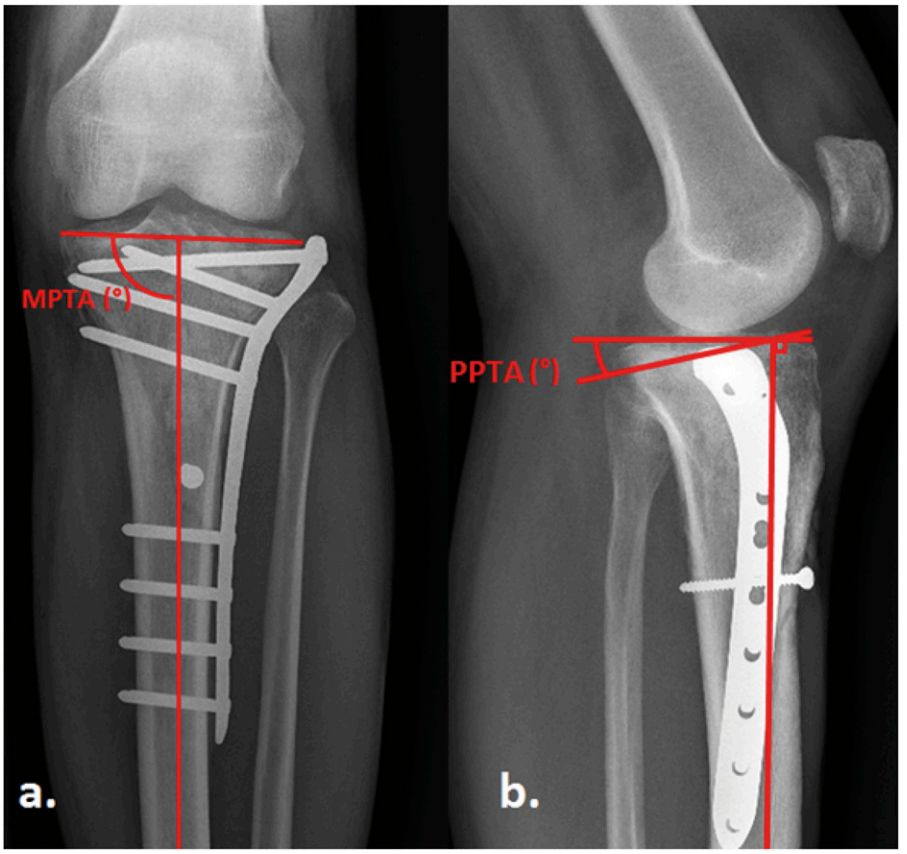

Fig. 2

Proximal tibial alignment measurements. **Fig. 2-A** Coronal alignment, or medial proximal tibial angle (MPTA; normal range, 82° to 92°). **Fig. 2-B** Sagittal alignment, or posterior proximal tibial angle (PPTA; normal range, 4° to 14°).

any reoperations. If no response was received, a reminder was sent after 3 weeks. Written informed consent was obtained from all patients. The institutional review board of each center approved the study procedures (registry: 201800411), and the research was performed in accordance with the relevant guidelines and regulations. This study is reported in accordance with the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guideline[8].

Image Review

All images were reassessed by 2 authors (N.A., F.F.A.IJ.) to determine the fracture classification according to the AO/OTA system[9]. Follow-up radiographs were assessed to verify whether or not patients had undergone conversion to TKA. Measurements were performed in a medical image viewer (Sectra UniView). Radiographs and CT scans were made using standard settings for the x-ray tube or CT scanner. All measurements represented a consensus by the 2 observers (i.e., the observers performed the measurements together).

Preoperative Fracture Assessment

Preoperative CT scans were assessed in the axial, sagittal, and coronal planes. The largest gap and step-off within any of these 3 planes was determined and reported (Fig. 1).

Postoperative Fracture Assessment

The quality of the fracture reduction and tibial alignment was evaluated on radiographs made ≤2 weeks postoperatively, using 4 radiographic parameters: articular fracture reduction, coronal alignment, sagittal alignment, and condylar widening. Fracture reduction was assessed by measuring the residual intra-articular incongruity (maximum gap and step-off). Coronal alignment was assessed by measuring the medial proximal tibial angle (MPTA) on the anteroposterior radiograph, and sagittal alignment was assessed by measuring the posterior proximal tibial angle (PPTA) on the lateral radiograph (Fig. 2). Condylar widening was assessed as described by Johannsen et al. (Fig. 3)[10]. Measurements were considered adequate if they were within the normal range. The articular reduction was considered adequate when both the gap and step-off were <2 mm; coronal alignment, when the MPTA was 87° ± 5°; sagittal alignment, when the PPTA was 9° ± 5°; and condylar widening, when it was between 0 and 5 mm[11-13].

Statistical Analysis

Mann-Whitney U and chi-square tests were performed to assess differences in baseline characteristics between responders and nonresponders. Critical cutoffs for the preoperative gap and

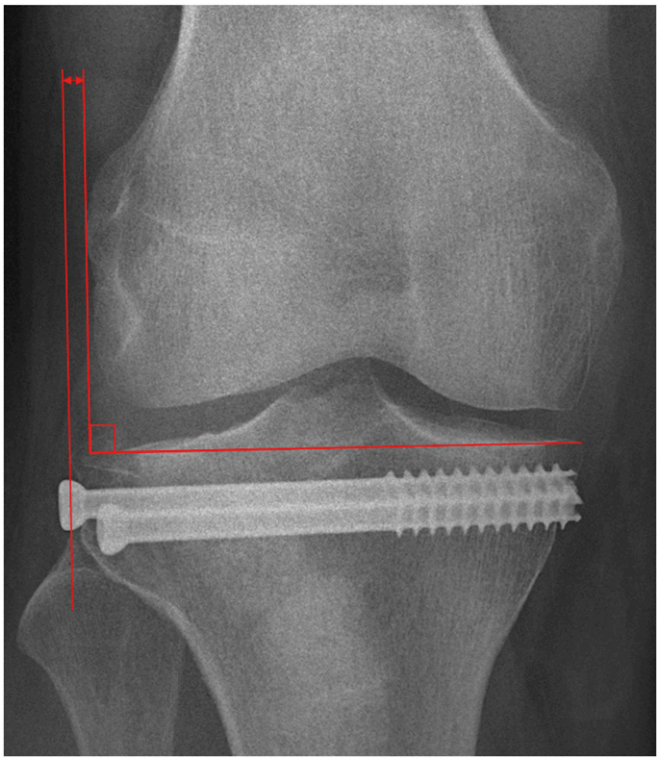

Fig. 3

Condylar widening measurement. Lateral condylar widening (normal range, 0 to 5 mm) is measured by drawing 2 lines perpendicular to the medial tibial articular surface, one along the most lateral aspect of the distal femoral condyle and the other along the most lateral aspect of the proximal tibia. The measured distance between these lines is considered condylar widening.

step-off were determined by identifying the point that maximized sensitivity and specificity after plotting a receiver operating characteristic (ROC) curve. For each of the 6 measurements of interest, patients were stratified into groups on the basis of the identified cutoff value or normal range, and Kaplan-Meier curves were plotted for the groups. Log-rank tests were performed to assess differences between these groups. The proportionality assumption was assessed by inspecting log-minus-log plots and by adding an interaction term with time. Cox regression was performed to identify the adjusted hazard ratio (HR, representing the relative risk of a complication based on comparison of the event rates) for conversion to TKA that was associated with each measurement after correction for potential confounders (age, sex, smoking, body mass index [BMI], and AO/OTA classification)[14-16]. The intraobserver variability of each measurement was determined by repeating the measurements for 20 cases (with a >1-month interval) and calculating the intraclass correlation coefficient (ICC). We used a 2-way mixed, single-measurement model with absolute agreement. Statistical analysis was performed using SPSS (version 23; IBM). A p value of <0.05 was considered significant.

Source of Funding

There was no external funding source for this study.

Results

Patient Characteristics

Between 2003 and 2018, 1,035 patients were treated surgically for a tibial plateau fracture. Of these, 5 had an amputation, 45 were <18 years old, 97 were deceased at the time of follow-up, and 18 had an unknown address. Eight additional patients were excluded because of insufficient quality of the postoperative radiographs, leaving 862 patients eligible for follow-up. All of these patients were approached, and 477 responded (55% response rate). Table I displays patient demographics. Sixty-seven (14%) of the patients had conversion to TKA and none had conversion to unicompartmental knee arthroplasty. Comparison of the responders with the nonresponders demonstrated small differences in age (mean and standard deviation, 53 ± 14 versus 50 ± 16 years, respectively, p = 0.011) and in the proportion of women (68% versus 61%, p = 0.038).

Preoperative Fracture Assessment

Patients who underwent conversion to TKA had a significantly wider preoperative gap (10.1 ± 6.5 versus 6.6 ± 5.9 mm, p < 0.001) and greater step-off (10.6 ± 7.3 versus 7.5 ± 6.1 mm, p < 0.001) compared with those without conversion to TKA. The intraobserver comparison showed an ICC of 0.79 for

TABLE I Patient Characteristics (N = 477)

Age* *(yr)*	53 ± 14
Female	326 (68%)
BMI* *(kg/m²)*	26.1 ± 5
Smoking	113 (24%)
AO/OTA classification	
41-B1	27 (6%)
41-B2	75 (16%)
41-B3	260 (55%)
41-C1	24 (5%)
41-C2	9 (2%)
41-C3	82 (17%)
Operative treatment	
Plate osteosynthesis	393 (82%)
Screw osteosynthesis	84 (18%)
Conversion to knee arthroplasty	67 (14%)
Unicompartmental knee arthroplasty	0 (0%)
Total knee arthroplasty	67 (14%)
Follow-up* *(yr)*	6.5 ± 4.1
Reinterventions during follow-up	
Elective removal of osteosynthesis material	186 (39%)
Reoperation for fracture-related infection	15 (3%)
Revision surgery for residual displacement	8 (2%)
Reoperation for meniscal or ligamentous repair	7 (2%)

*The values are given as the mean ± standard deviation.

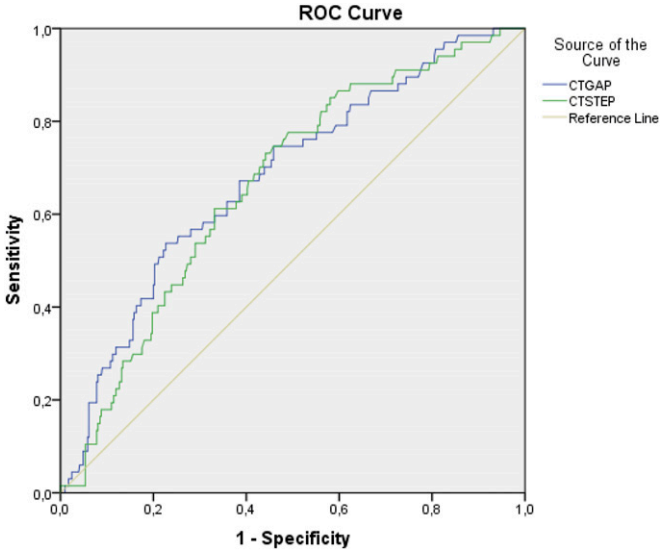

Fig. 4

Receiver operating characteristic (ROC) curve demonstrating the association of preoperative fracture gap (CTGAP, blue) and step-off (CTSTEP, green) with conversion to total knee arthroplasty.

the gap and 0.78 for step-off. The area under the ROC curve was 0.68 for the preoperative gap and 0.67 for step-off (Fig. 4). The critical cutoff values derived from the ROC analysis were 8.5 mm for the preoperative gap and 6 mm for the step-off.

Postoperative Fracture Assessment

The group with conversion to TKA had significantly higher percentages of patients with inadequate condylar widening (25% versus 13%, p = 0.008), inadequate articular congruity (64% versus 44%, p = 0.002), coronal malalignment (46% versus 22%, p < 0.001), and sagittal malalignment (64% versus 21%, p < 0.001) compared with patients who did not undergo conversion to TKA and still had their own, native knee (Table II). The intraobserver comparison showed an ICC of 0.8 for condylar widening, 0.8 for articular incongruity, 0.7 for MPTA, and 0.8 for PPTA.

Native Knee Survival

Kaplan-Meier survival curves showed an overall survival rate of 84% for the native knee (free of conversion to TKA) at 10-year follow-up. When stratified on the basis of the critical cutoff value for the preoperative gap, the 10-year knee survival was 91% in the group with a preoperative gap of ≤8.5 mm versus 67% in the group with a gap of >8.5 mm (Fig. 5). When stratified on the basis of a preoperative step-off of ≤6 versus >6 mm, the survival rates were 93% and 75%, respectively. When stratified on the basis of tibial alignment, 10-year survival was 88% in patients with adequate coronal alignment versus 72% in patients with malalignment. When stratified on the basis of adequate versus inadequate sagittal alignment, 10-year survival was 92% versus 63%, respectively. The log-rank test showed that the difference between the survival curves was significant for each measurement (p ≤ 0.011).

Independent Risk Factors for Conversion to TKA

An HR of 3.3 (95% confidence interval [CI] = 2.0 to 5.4, p < 0.001) was found for patients with a preoperative gap of >8.5 mm, meaning that the instantaneous rate of receiving a TKA at any time during follow-up was 3.3 times higher among patients with a gap of >8.5 mm compared with those with a gap of ≤8.5 mm. Patients with a step-off of >6.0 mm showed an HR of 3.6 (95% CI = 2.0 to 6.3, p < 0.001). Similar results were found after adjusting for confounders (Table III).

Condylar widening was not associated with conversion to TKA after adjusting for confounders. However, certain other postoperative measurements were associated with conversion. The risk of conversion to TKA was higher among those with an abnormal MPTA (HR = 1.6, 95% CI = 1.0 to 2.8, p = 0.05) and PPTA (HR = 3.7, 95% CI = 2.1 to 6.3, p = 0.001). With regard to articular incongruity, displacement of 2 to 4 mm did not significantly affect the risk compared with the reference group (<2.0 mm). Although the adjusted HR of 0.6 corresponded to an estimated 40% decrease in the (instantaneous) risk of conversion to TKA, the estimated HR was also consistent with an increase of up to 20% according to the CI (HR = 0.6, 95% CI = 0.3 to 1.2, p = 0.176). As the gap or step-off increased beyond 4 mm, the risk of conversion to TKA increased as well. The conversion rate among those with a gap or step-off between 4.0 and 6.0 mm was 2.7 (95% CI = 1.4 to 5.0, p = 0.002) times higher than among the reference group. A gap or step-off of >6.0 mm further increased the risk of conversion to TKA (HR = 5.0, 95% CI = 2.4 to 11.2, p <0.001).

Discussion

Achieving anatomical restoration of the articular surface, adequate tibial alignment, and joint stability are the main goals in surgical treatment of tibial plateau fractures. However, comminuted fractures do not always allow for anatomical reduction. Controversy remains regarding the impact of articular incongruity and tibial alignment on clinical outcome. Our study presents a cohort of surgically treated tibial plateau fractures in which radiographic parameters measuring pre- and

TABLE II Pre- and Postoperative Measurements for Patients with and without Conversion to TKA

Measurement	Conversion to TKA: Yes (N = 67)	Conversion to TKA: No (N = 410)	P Value*
Preoperative			
Gap > 8.5 mm	36 (54%)	99 (24%)	<0.001
Step-off > 6.0 mm	49 (73%)	185 (45%)	<0.001
Postoperative			
Condylar widening > 5 mm	17 (25%)	53 (13%)	0.008
Articular incongruity > 2 mm	43 (64%)	179 (44%)	0.002
MPTA < 82° or > 92°	31 (46%)	90 (22%)	<0.001
PPTA < 4° or > 14°	43 (64%)	87 (21%)	<0.001

*All p values were significant.

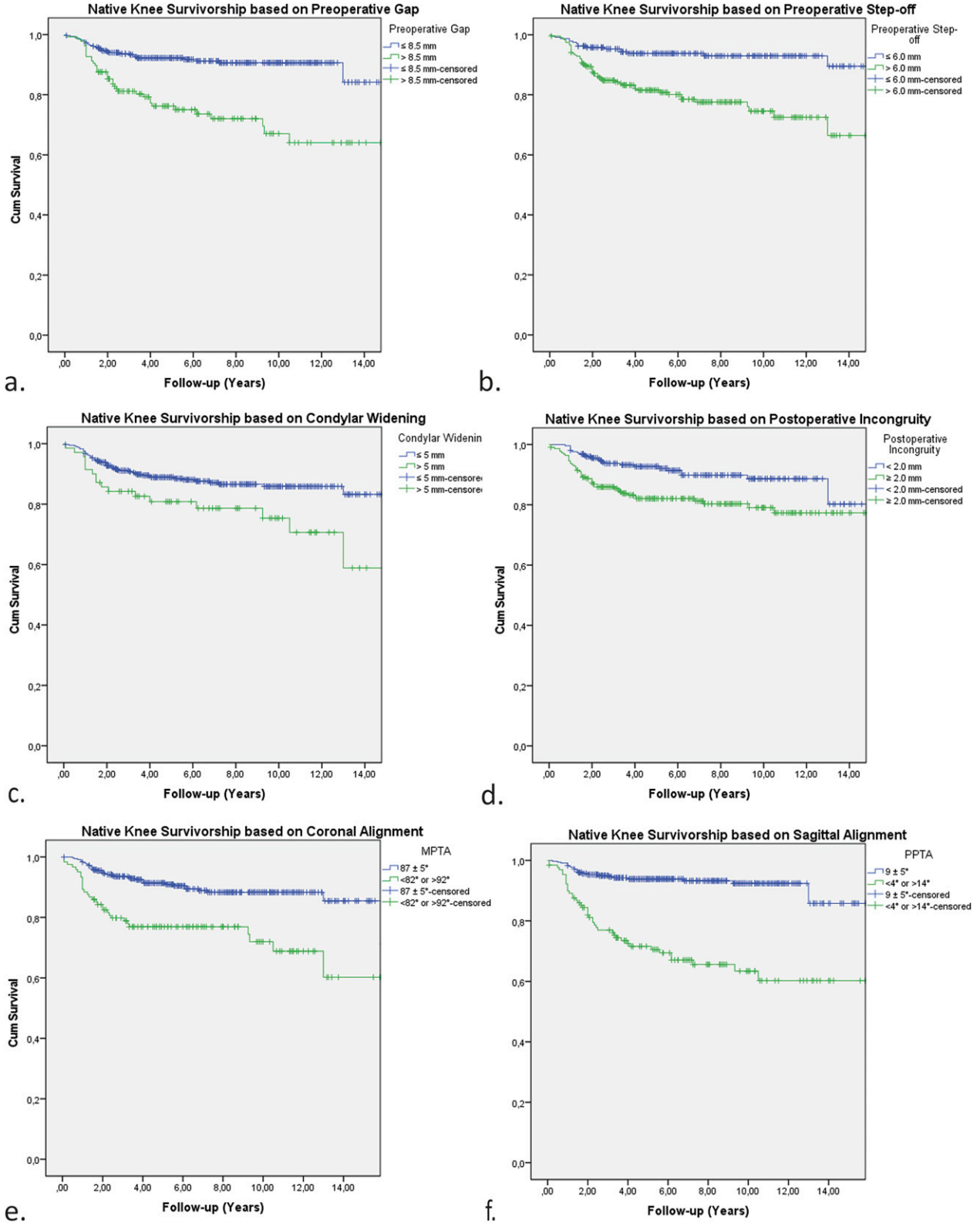

Fig. 5

Kaplan-Meier survival curves comparing groups stratified on the basis of preoperative gap (log-rank $p < 0.001$) (**Fig. 5-A**) and step-off (log-rank $p < 0.001$) (**Fig. 5-B**), condylar widening (log-rank $p = 0.011$) (**Fig. 5-C**), postoperative articular incongruity (log-rank $p = 0.002$) (**Fig. 5-D**), coronal alignment (log-rank $p < 0.001$) (**Fig. 5-E**), and sagittal alignment (log-rank $p < 0.001$) (**Fig. 5-F**).

TABLE III Multivariate Analysis of the Association of Radiographic Characteristics with Conversion to TKA

Measurement	Unadjusted HR (95% CI)	P Value	Adjusted HR* (95% CI)	P Value
Preoperative				
Gap > 8.5 mm	3.3 (2.0-5.4)	<0.001†	2.6 (1.5-4.5)	<0.001†
Step-off > 6.0 mm	3.6 (2.0-6.3)	<0.001†	3.0 (1.6-5.6)	<0.001†
Postoperative				
Condylar widening > 5 mm	2.0 (1.1-3.5)	0.013†	1.2 (0.7-2.1)	0.59
MPTA < 82° or > 92°	2.9 (1.8-4.7)	<0.001†	1.6 (1.0-2.8)	0.05†
PPTA < 4° or > 14°	5.2 (3.2-8.7)	<0.001†	3.7 (2.1-6.3)	<0.001†
Articular incongruity				
<2.0 mm (reference)	—	—	—	—
2.0-4.0 mm	0.9 (0.5-1.9)	0.919	0.6 (0.3-1.2)	0.176
>4.0-6.0 mm	5.0 (2.8-9.2)	0.006†	2.7 (1.4-5.0)	0.002†
>6.0 mm	5.2 (2.4-11.3)	<0.001†	5.0 (2.4-11.2)	<0.001†

*Adjusted for age, sex, smoking, BMI, and AO/OTA classification. †Significant.

postoperative fracture displacement were found to be associated with clinical outcome in terms of conversion to TKA at the time of follow-up. Assessment of preoperative CT scans indicated that substantial initial fracture displacement was independently associated with the need for conversion to TKA. Assessment of postoperative radiographs demonstrated that sagittal and coronal malalignment were strongly associated with conversion to TKA. In contrast to common belief, postoperative gaps or step-offs of <4 mm were not associated with an increased risk of TKA. However, more severe postoperative articular incongruity of >4 mm was associated with an increased risk of conversion to TKA.

Osteoarthritis may still develop after adequate fracture reduction because of extensive irreversible damage to the articular surface caused by the initial trauma. Several studies have indicated that the severity of the fracture is predictive of early-onset osteoarthritis[6,17]. Additionally, Parkkinen et al. showed that a preoperative step-off of >3.4 mm in medial tibial plateau fractures was predictive of the development of moderate to severe osteoarthritis[7]. Nevertheless, literature on the association between initial fracture displacement and the risk of conversion to TKA after surgical treatment of tibial plateau fractures is still limited. In line with previous studies[6,7,17], we found that substantial initial fracture displacement was a strong predictor of the development of progressive osteoarthritis eventually requiring conversion to TKA. In addition, our results indicated that not only the step-off but also the gap was predictive of the clinical outcome[7]. Knowledge about the association between substantial initial fracture displacement and an increased risk of conversion to TKA at the time of follow-up may aid in expectation management and patient counseling about the prognosis.

Postoperative assessments of residual incongruity and tibial alignment are essential for decision-making about revision surgery and patient counseling about the prognosis. Much controversy exists regarding the degree of residual displacement that can be accepted. Residual displacement of <2 mm as measured by the gap or step-off is generally considered an adequate reduction[11,12]. Recent studies have reconfirmed that a residual step-off of >2 mm, as measured on a postoperative radiograph, is associated with worse functional outcomes[3,7]. However, a review by Giannoudis et al. showed that controversy remains regarding the degree of articular incongruity that can be tolerated in tibial plateau fracture management[18]. Our recent study demonstrated that a fracture gap or step-off of ≤4 mm, as measured on CT scans, could result in good functional outcomes in patients who opt for nonoperative fracture management[19]. In addition to these studies, our current results seem to indicate that initial displacement of up to 4 mm does not affect the risk of conversion to TKA. Therefore, the arbitrary 2-mm limit for gaps and step-offs in tibial plateau fractures might be revisited. However, our study did show that greater postoperative incongruity, with displacement exceeding 4 mm, was associated with an increased risk of TKA. Although much literature has focused on residual articular incongruity, hardly any studies have reported on the relationship between the achieved tibial alignment and functional outcome. Recently, Van den Berg et al. reported that sagittal malalignment was associated with worse outcomes and emphasized the importance of restoring the sagittal alignment when treating posterior tibial plateau fractures[13]. Additionally, Parkkinen et al. showed that coronal malalignment was associated with the development of osteoarthritis and worse pain[3,7]. However, those studies were limited by small sample sizes and a focus on specific fracture types, and they did not provide HRs. Our study adds to the literature by including >450 patients with all tibial plateau fracture types. Our results indicated that both the postoperative coronal and sagittal malalignment of the tibia were strong predictors of conversion to TKA. Therefore, surgeons should be aware of the importance of restoring tibial alignment when performing surgical management of complex tibial plateau fractures.

This study has several limitations. First, selection bias caused by loss to follow-up and nonresponse is inherent to a cross-sectional study design. Second, meniscal and/or ligamentous injuries might be considered an important confounder, but it was challenging to identify whether the patients in this retrospective study had any meniscal injuries because magnetic resonance imaging or arthroscopy is not regularly performed within our clinics. Nevertheless, we gathered as much information as possible about the impact of concomitant soft-tissue injuries. All patients were contacted and asked whether they had undergone any reintervention, and patient files were verified. Only 7 (0.15%) of 477 patients underwent a reoperation for meniscal or ligamentous repair. Future studies should incorporate concomitant soft-tissue injury and assess its impact on patient outcome. Third, not all radiographs were made by the same radiology technician, and some radiographs may not have been aligned perfectly in the anteroposterior and lateral views or may have had slight differences in magnification since the radiographs were not calibrated. However, this is inherent to clinical practice. Furthermore, there are concerns regarding the interobserver reliability of radiographic measurements even though these measurements are still the gold standard in clinical practice[5,20]. Gap and step-off measurements in particular are prone to interobserver variability[21,22], although measurements of tibial alignment have shown good reliability[23,24]. Nevertheless, intraobserver measurements within this study showed good reliability for all measurements. Fourth, the number of patients who underwent conversion to TKA was limited since conversion to TKA is relatively uncommon. Finally, our findings may be parochial to the clinical environment from which the substrate was developed and therefore cannot be assumed to be generalizable to other clinical environments. Performance in other clinical contexts should be tested to ensure validity. Given these limitations, this work can only be considered hypothesis-generating and not prescriptive.

Worldwide, fracture displacement and tibial alignment are generally still determined on radiographs and 2-dimensional CT slices. However, more advanced 3-dimensional (3D) imaging techniques are increasingly used in treatment of tibial plateau fractures[25]. For example, we recently introduced a novel 3D technique to measure intra-articular incongruity in tibial plateau fractures[21]. Measurements of sagittal alignment of the tibia might also be improved by using 3D technology[26]. We envision that novel 3D measurements will be increasingly used in addition to current classification systems in order to evaluate the true fracture extent and estimate the prognosis. Furthermore, we chose conversion to TKA as the sole end point in this study since it is a commonly used and unambiguous end point, but the results of surgical treatment could also be evaluated using outcome measures. Future research should therefore focus on the association between radiographic measurements and the risk of poor results as measured by patient-reported outcomes.

In summary, this large multicenter study of medium-term clinical outcomes after tibial plateau fracture surgery demonstrated that substantial initial fracture displacement is a strong independent predictor of conversion to TKA. Moreover, this study showed that postoperative incongruity of >4 mm and sagittal and coronal malalignment were strong independent predictors of conversion to TKA at the time of follow-up. These findings can be used as a guideline for counseling patients with complex tibial plateau fractures and could help to estimate the prognosis. ■

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Cementless Versus Cemented Total Knee Arthroplasty

Concise Midterm Results of a Prospective Randomized Controlled Trial

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Background: We previously reported the 2-year results of a prospective randomized controlled trial of cementless versus cemented total knee arthroplasty (TKA) implants of the same design. The purpose of the present study was to provide concise results at intermediate-term follow-up.

Methods: The original study included 141 TKAs (76 performed without cement and 65 performed with cement). Since then, 8 patients died and 4 withdrew. Of the remaining 129 patients, 127 (98%) were available for analysis. Survivorship analysis was performed; Oxford Knee, Knee Society, and Forgotten Joint Scores were calculated; and radiographs reviewed. Mean follow-up was 6 years.

Results: The survivorship free of any revision was 100% in both groups. There were no differences between the groups in any patient-reported functional outcome measure ($p = 0.2$ to 0.5). However, a higher percentage of patients in the cementless TKA group were either extremely or very satisfied with their overall function ($p = 0.01$). Radiographically, there was no evidence of implant loosening in either group.

Conclusions: At 6 years, there were no differences between cementless and cemented TKA implants of the same design in terms of survivorship, clinical, or radiographic outcomes.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

The number of total knee arthroplasty (TKA) procedures performed annually continues to rise, particularly in younger, more active patients[1]. Historically, cement has been the gold standard for fixation, but aseptic loosening remains a leading cause of failure after primary TKA[2,3]. Cementless fixation has garnered substantial interest because of the potential for biologic fixation and improved long-term survivorship[4].

Early designs of cementless TKA implants were associated with high rates of failure due to poor designs and fixation surfaces such as mesh coatings, patch coatings, and sintered beads[5-9]. As implant design and metallurgy evolved, contemporary cementless implants have demonstrated improved clinical outcomes and survivorship at short-term follow-up[10-12]. However, some studies have suggested higher rates of early aseptic loosening in association with cementless fixation compared with cement fixation[13]. We previously reported the short-term results of a prospective randomized controlled trial comparing cementless and cemented TKA implants of the same contemporary design[14]. At 2 years, there were no revisions or reoperations in either group and patient-reported clinical outcome scores were equivalent between the groups.

While the short-term survivorship and clinical outcomes of cementless TKA implants are excellent, there is a lack of Level-I evidence at intermediate to long-term follow-up. The purpose of the present study was to provide the intermediate-term follow-up of the previous prospective randomized controlled trial and to compare the intermediate-term implant survivorship, clinical outcomes, and radiographic results between cementless and cemented TKA implants of the same design.

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H592).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H593).

Materials and Methods

After receiving institutional review board approval, we retrospectively reviewed the records on a previously published prospective randomized controlled trial (ClinicalTrials.gov identifier: NCT03683992) including 141 primary TKAs performed between 2014 and 2016[14]. The exclusion criteria were a diagnosis of inflammatory arthritis, a body mass index (BMI) of >40 kg/m^2, active or suspected infection in the joint or body, prior fracture of the knee (patella, femur, or tibia), prior open surgery involving the knee, a neuromuscular disorder, or grossly osteoporotic bone or bone defects on preoperative radiographs. The surgical procedures were performed by 4 fellowship-trained total joint arthroplasty surgeons. Each surgeon had a 1:1 block-randomization table with random block sizes to ensure similar group sizes for each surgeon. After randomization, there was no crossover between treatment groups. Routine clinical and radiographic follow-up was completed at 1 year, 2 years, 5 years, and every 5 years thereafter. Patients who were unavailable for in-person follow-up were contacted by telephone to complete patient-reported outcome instruments and were asked to return in person for radiographic and clinical follow-up.

The original randomized controlled trial included 141 TKAs (76 performed without cement and 65 performed with cement)[14]. All TKAs were performed with a cruciate-retaining prosthesis (Triathlon; Stryker). Simplex (Stryker) bone cement was utilized for the procedures that were performed with cement. The cementless femoral implant has a 3-dimensional surface with multiple layers of cobalt-chromium beads and a Peri-Apatite (Stryker) coating. The cementless tibial component (Triathlon Tritanium tibial baseplate; Stryker) has a 3-dimensionally printed highly porous titanium coating with a keel and 4 cruciform pegs. None of the TKAs included in either group involved patellar resurfacing.

In the cemented implant group, the mean age (and standard deviation) was 63 ± 7.6 years, the mean BMI was 31.3 ± 4.7 kg/m^2, and 52% of the patients were female. In the cementless implant group, the mean age was 61 ± 7.0 years, the mean BMI was 31.1 ± 5.2 kg/m^2, and 48% of the patients were female. There were no differences between the groups in terms of age ($p = 0.1$), sex ($p = 0.1$), or BMI ($p = 0.8$). Since the original publication, 8 patients died and 4 withdrew from the study (Fig. 1). Of the remaining 129 patients, 127 (98%) were available for analysis at a minimum 5-year follow-up. The mean duration of follow-up was 6 years (range, 5 to 8 years), with no difference between the groups ($p = 0.9$).

Revisions, reoperations, and complications were identified at the most recent follow-up on the basis of a manual chart review and by contacting patients. Revision was defined as any removal of the prosthesis, including the femoral component, tibial component, and/or polyethylene liner. Preoperative and postoperative functional outcome was assessed with use of the Oxford Knee Score, Knee Society Score, and the Forgotten Joint Score[15-17]. Patients were also asked to rate their knee as a percentage of "normal" (maximum of 100%, equivalent to completely normal), their overall health, and their satisfaction with their overall function.

Serial radiographs were also reviewed for all TKAs. Components were assessed for the presence of radiolucent lines or a change in implant position. Loosening was defined by the presence

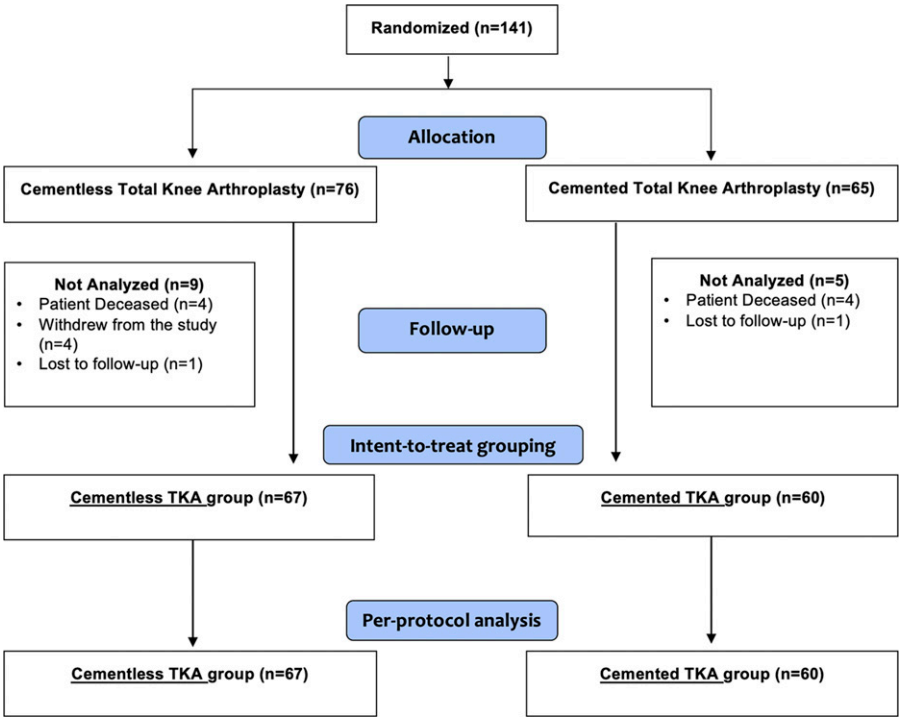

Fig. 1

CONSORT diagram.

TABLE I Patient-Reported Outcome Scores for Cemented and Cementless TKA Implant Groups

	Mean 2-Year Follow-up			Mean 6-Year Follow-up		
	Cemented (N = 65)	Cementless (N = 76)	P Value	Cemented (N = 53)	Cementless (N = 62)	P Value
Postoperative Oxford Knee Score	39.6 ± 9.1	41.0 ± 7.5	0.3	40.94 ± 7.7	41.77 ± 7.76	0.5
Change in Oxford Knee Score	17.3 ± 10.5	19.7 ± 8.7	0.2*	−0.28 ± 9.34	2.1 ± 10.14	0.2†
Postoperative Knee Society function score	75.6 ± 17.9	78.5 ± 17.5	0.3	76.0 ± 18.11	78.5 ± 19.03	0.5
Change in Knee Society function score	33.5 ± 19.7	39.2 ± 25.2	0.2*	1.9 ± 23.5	−1.2 ± 23.5	0.5†
Forgotten Joint Score	66.6 ± 33.0	61.5 ± 31.1	0.3	61.19 ± 28.73	67.66 ± 25.84	0.2
Percentage of normal knee *(%)*	88.2 ± 12.0	87.4 ± 14.5	0.7	80.2 ± 21.53	83.60 ± 18.45	0.3

*The change scores at mean 2-year follow-up are calculated from the difference between the 2-year postoperative scores and the baseline (preoperative) scores. The scores are compared between the cemented and cementless groups using the independent-samples t test. †The change scores at mean 6-year follow-up are calculated from the difference between the 6-year postoperative scores and the baseline (preoperative scores). The scores are compared between the cemented and cementless groups using the independent-samples t test.

of a continuous radiolucent line measuring ≥2 mm or component position change of >2 mm[18,19].

Statistical Analysis

Descriptive statistics (mean, standard deviation, range, count, percentage) were calculated for continuous and categorical data. All continuous variables were analyzed with independent-samples t tests. Survivorship rates free of any revision or any reoperation were calculated for patients who were available at the most recent follow-up. The level of significance was set at $p < 0.05$. All analyses were conducted with use of SPSS for Windows (version 22; IBM).

Source of Funding

Research support was provided to the investigating institution by Stryker, Inc., the manufacturer of the implant under investigation.

Results

Survivorship Free of Revision and Reoperation

At the most recent follow-up, the rate of implant survival free of any revision was 100% in both groups. Only 1 patient underwent reoperation in the cement group, and no patient underwent reoperation in the cementless group. The 1 patient who had a reoperation underwent patellar resurfacing at 5 years for the treatment of persistent anterior knee pain and patellar arthritis. Thus, the rate of implant survival free of any reoperation was 100% in the cementless group and 98.5% in the cement group at the most recent follow-up.

Clinical Outcomes

At the most recent follow-up, the mean Oxford Knee Score was 41.8 ± 7.8 in the cementless group and 40.9 ± 7.7 in the cement group ($p = 0.5$) (Table I). There were no differences between the groups in terms of the Knee Society Score ($p = 0.5$), the Forgotten Joint Score ($p = 0.2$), or the percentage-of-normal score ($p = 0.3$) (Table I). There were no differences between the 2 and 6-year scores for any of the patient-reported outcomes, including the Oxford Knee Score, Forgotten Joint Score, Knee Society Score, or percentage-of-normal score.

The percentage of patients who were extremely or very satisfied with their overall function was greater in the cementless group than in the cement group (84% versus 66%; $p = 0.01$) (Table II). There were no differences between the groups in terms of the overall health rating ($p = 0.4$).

Radiographic Outcomes

Radiographically, there was no evidence of implant loosening in either group (Figs. 2-A and 2-B). The percentage of knees with radiolucent lines was 31% in the cementless group and 42% in the cement group ($p = 0.333$).

Discussion

The use of cementless fixation during primary TKA is rapidly growing, with >14% of all primary TKAs in the United States being performed with cementless fixation[20]. As the number of cementless TKAs performed annually continues to

TABLE II Patient Satisfaction with Overall Function

	Cemented (N = 53)	Cementless (N = 62)	P Value
Satisfaction with overall function			0.01
Extremely satisfied	39.6%	59.7%	
Very satisfied	26.4%	24.2%	
Quite satisfied	9.4%	4.8%	
Somewhat satisfied	15.1%	6.5%	
Slightly satisfied	7.5%	1.6%	
Not satisfied	2.0%	1.6%	
Uncertain	0%	1.6%	

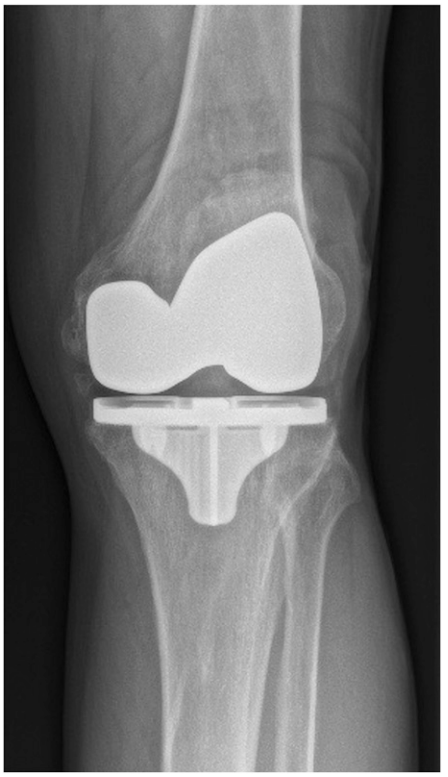

Fig. 2-A

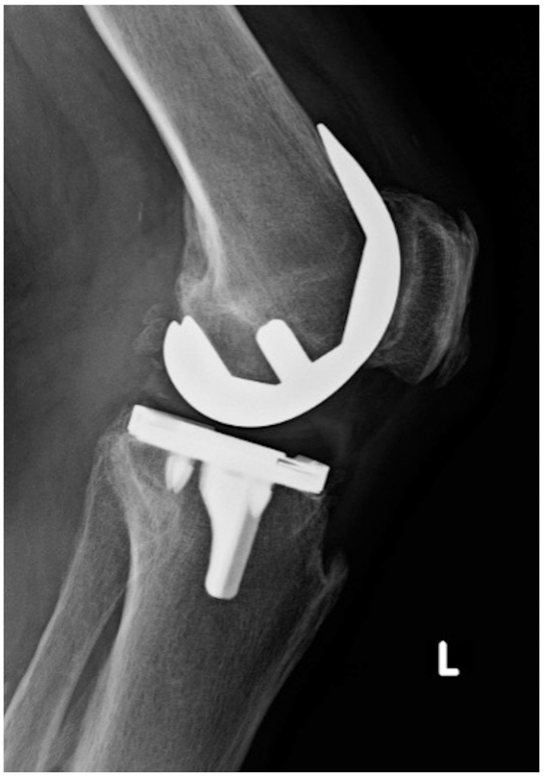

Fig. 2-B

Figs. 2-A and 2-B Anteroposterior (**Fig. 2-A**) and lateral (**Fig. 2-B**) radiographs showing a cementless TKA implant at 7 years postoperatively.

rise, understanding the survivorship, clinical outcomes, and radiographic outcomes of TKA procedures performed with and without cement is critical. At intermediate-term follow-up of the patients who were included in this prospective randomized controlled trial, we found that cemented and cementless TKA implants of the same design had excellent and equivalent survivorship, clinical outcomes, and radiographic outcomes. Importantly, there were no revisions for aseptic loosening in either group.

The excellent implant survivorship found with the particular cementless TKA implant in the present study is consistent with previously published findings[10,21,22]. Miller et al., in a retrospective matched case-control study of 400 TKAs comparing cementless and cemented implants, found equivalent survivorship and improvements in the Knee Society Score at an average of 2 years of follow-up[21]. In that series, 1 cementless implant (0.5%) and 5 cemented implants (2.5%) were revised for aseptic loosening. In a recent review of the American Joint Replacement Registry (AJRR) evaluating 28,631 TKAs that were performed with the same cementless implant as was used in the present study, Nam et al. found a 5-year survivorship of 98.9% compared with a survivorship of 98.4% for the cemented version of the same implant[22]. A systematic review of 20 studies evaluating the survivorship and clinical outcomes with the same cementless TKA that was used in the present study demonstrated a 99.2% rate of implant survival free of any aseptic revision at 3.8 years[10]. The present Level-I study supports the finding that excellent survivorship is maintained with the Stryker Triathlon cementless TKA implant at intermediate-term follow-up (mean, 6 years).

In our series, there were no differences between the cemented and cementless implant groups in terms of patient-reported functional outcome scores. The mean Knee Society function score in the cementless group was 78.5, which is similar to what has been previously published[10]. Carlson et al. reported a mean Knee Society function score of 82.7 in their systematic review of 20 studies evaluating the same cementless TKA implant[10]. Several prior studies also have demonstrated equivalent patient-reported outcome scores between cemented and cementless TKA implants at intermediate-term follow-up[21,23]. Interestingly, in the present study, we found that a higher percentage of patients in the cementless group were extremely or very satisfied with their overall function compared with the percentage in the cemented group. Further study is required to better understand this difference and whether it persists over time, as there were no differences in satisfaction with overall function at short-term follow-up.

There were no differences between the cementless and cemented implant groups in terms of radiographic findings. In both groups, all components were well fixed radiographically. Radiolucent lines were present in each group, and the incidence of radiolucent lines was not different between groups. Radiolucent lines are not uncommon at intermediate-term follow-up after TKA performed with or without cement[23,24]. Costales et al. reported that the rate of radiolucent lines was 43% in

association with older-generation cementless tibial components and 81% in association with cementless femoral components after a mean duration of follow-up of 9.6 years[24]. The presence of radiolucent lines did not correlate with long-term clinical outcomes, similar to the findings of the present study.

The present study had several limitations. First, it evaluated the intermediate-term follow-up at 6 years, and differences between cementless and cemented implants in terms of survivorship, clinical outcomes, and radiographic results may arise over the long term. However, it is important to monitor implants at regular intervals (short, intermediate, and long-term follow-up), which is why we have reported the results at this interval. Second, as described in the original publication, strict indications were utilized for cementless TKA and thus for study inclusion. Patients with severe osteoporosis or bone defects were excluded. Thus, the generalizability of these results should be interpreted with caution. Third, 4 patients withdrew from the study and 8 patients died prior to this follow-up. None of the 8 patients who died had a revision. Last, while there were no differences in patient-reported outcome scores, the present study may not be powered to detect such a difference. The study was powered to detect differences in the Oxford Knee Score but may not be powered to detect differences in other outcome measures.

In conclusion, this prospective randomized controlled trial demonstrated that, at 6 years, there were no differences in survivorship, radiographic outcomes, or clinical outcomes between cementless and cemented TKA implants of the same design. Long-term surveillance is necessary to determine if differences in survivorship or clinical outcomes will arise over time. ■

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A commentary by Nathanael D. Heckmann, MD, is linked to the online version of this article.

Pain Relief After Total Knee Arthroplasty with Intravenous and Periarticular Corticosteroid

A Randomized Controlled Trial

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Background: Total knee arthroplasty (TKA) is a cost-effective procedure, but it is also associated with substantial postoperative pain. The present study aimed to compare pain relief and functional recovery after TKA among groups that received intravenous corticosteroids, periarticular corticosteroids, or a combination of both.

Methods: This randomized, double-blinded clinical trial in a local institution in Hong Kong recruited 178 patients who underwent primary unilateral TKA. Six of these patients were excluded because of changes in surgical technique; 4, because of their hepatitis B status; 2, because of a history of peptic ulcer; and 2, because they declined to participate in the study. Patients were randomized 1:1:1:1 to receive placebo (P), intravenous corticosteroids (IVS), periarticular corticosteroids (PAS), or a combination of intravenous and periarticular corticosteroids (IVSPAS).

Results: The pain scores at rest were significantly lower in the IVSPAS group than in the P group over the first 48 hours ($p = 0.034$) and 72 hours ($p = 0.043$) postoperatively. The pain scores during movement were also significantly lower in the IVS and IVSPAS groups than in the P group over the first 24, 48, and 72 hours ($p \leq 0.023$ for all). The flexion range of the operatively treated knee was significantly better in the IVSPAS group than in the P group on postoperative day 3 ($p = 0.027$). Quadriceps power was also greater in the IVSPAS group than in the P group on postoperative days 2 ($p = 0.005$) and 3 ($p = 0.007$). Patients in the IVSPAS group were able to walk significantly further than patients in the P group in the first 3 postoperative days ($p \leq 0.003$). Patients in the IVSPAS group also had a higher score on the Elderly Mobility Scale than those in the P group ($p = 0.036$).

Conclusions: IVS and IVSPAS yielded similar pain relief, but IVSPAS yielded a larger number of rehabilitation parameters that were significantly better than those in the P group. This study provides new insights into pain management and postoperative rehabilitation following TKA.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Total knee arthroplasty (TKA) is a cost-effective procedure, but 8% to 26.5% of patients have substantial postoperative pain[1]. Periarticular corticosteroids (PAS)[2-12] and intravenous corticosteroids (IVS)[13-17] have been demonstrated to be effective in providing acute pain relief and better mobilization after TKA. The present study aimed to compare pain relief and functional recovery after TKA among groups that received IVS, PAS, or a combination of both (IVSPAS). We hypothesized that patients receiving IVSPAS would report less postoperative pain and have better

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H483).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H484).

functional recovery than those receiving IVS, PAS, or a saline solution placebo (P) alone.

Materials and Methods

This parallel randomized clinical trial (RCT) was approved by the local research ethics committee and registered at ClinicalTrials.gov (NCT03901768). Written informed consent was obtained from the patients.

The CONSORT (Consolidated Standards of Reporting Trials) flow diagram is shown in Figure 1. Patients who underwent primary unilateral TKA were screened for eligibility. Patients who declined to give consent; had a history of chronic pain, insulin-dependent diabetes mellitus, or peptic ulcer disease; were chronic users of glucocorticoids, immunosuppressants, or immune-modulating agents, or of strong opioids such as morphine, fentanyl, hydromorphone, methadone, oxycodone, or meperidine; were a hepatitis B or C carrier; or had renal impairment (creatinine [Cr], >200 μmol/L) were excluded. The remaining patients were assigned to 1 of the 4 groups according to a computer-generated randomization sequence.

All procedures were performed by the same surgical team using standardized surgical techniques involving a medial parapatellar surgical approach and a cemented posterior-stabilized prosthesis. Local infiltration analgesia (LIA) was administered by the surgeon using the technique described by Kerr and Kohan[18]. The standard regimen used in LIA was a mixture of 40 mL of 0.75% ropivacaine, 0.5 mL of 1:200,000 adrenaline, and 30 mg of ketorolac in 60 mL of 0.9% saline solution.

Patients in the P group received 4 mL of intravenous 0.9% saline solution and the standard LIA. Patients in the IVS group received 16 mg of intravenous dexamethasone (4 mL of a 4 mg/mL dexamethasone solution) and the standard LIA. Patients in the PAS group received 4 mL of intravenous 0.9% saline solution and the standard LIA plus 40 mg of triamcinolone (1 mL of a 40-mg/mL triamcinolone solution). Patients in the IVSPAS group received the standard LIA plus 1 mL of 40-mg/mL triamcinolone and 16 mg of intravenous dexamethasone. The patients and all outcome assessors were blinded to the group assignments.

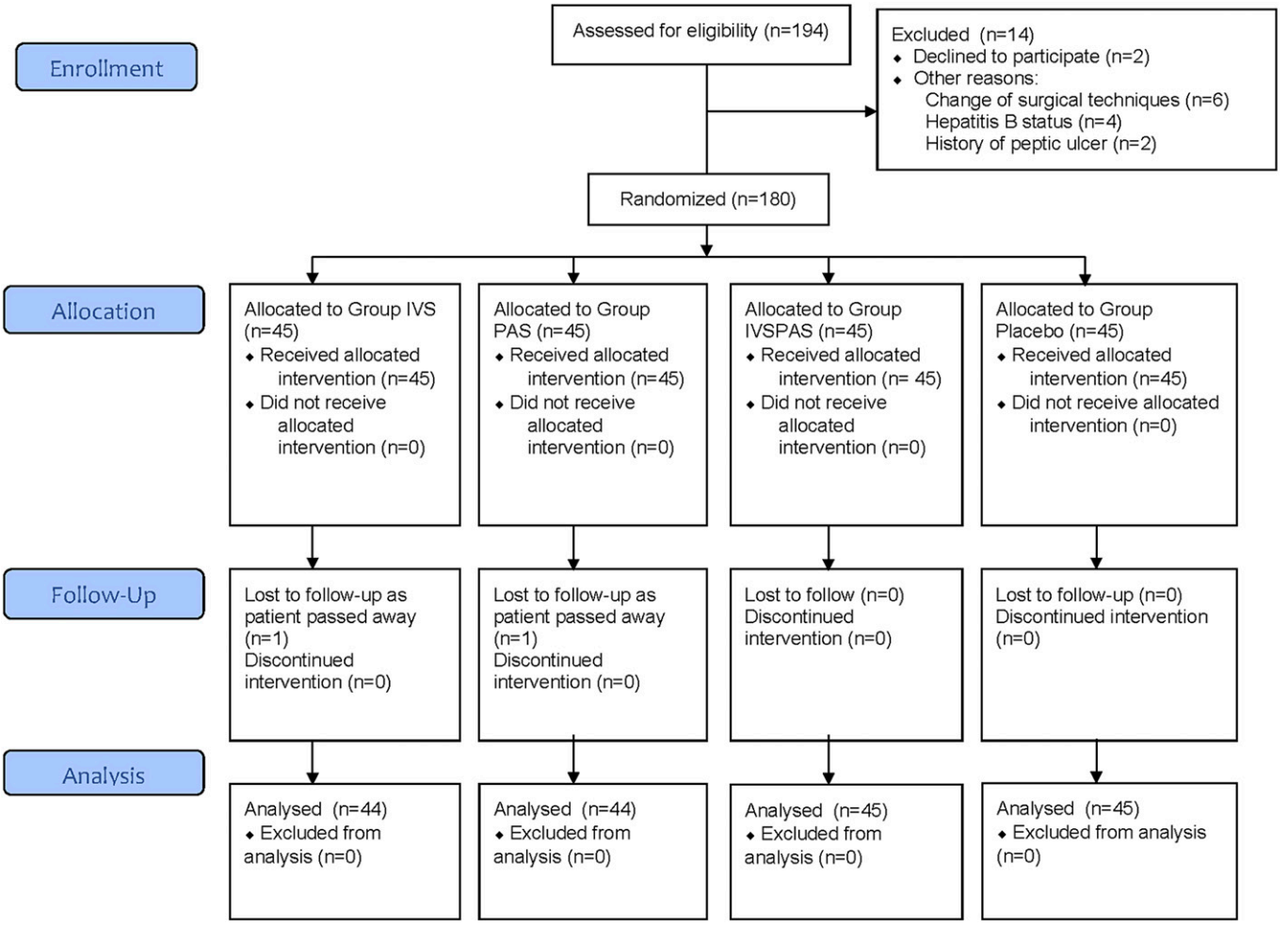

Fig. 1
CONSORT diagram for the study.

The baseline range of movement, quadriceps power, and pain in the operatively treated knee on a numeric rating scale (NRS) were assessed by a physiotherapist 1 day before the surgery, and the blood glucose concentration was measured.

All operations were performed under spinal anesthesia using 2.4 mL of 0.5% hyperbaric bupivacaine. Patients were sedated with a target-controlled infusion of propofol; the target concentration was set to 0.3 to 1.0 mg/mL using the Marsh pharmacokinetic model[19]. Premedication was not administered.

Hemoglobin and glucose concentrations were measured at 1 and 2 hours after intravenous administration of the study drugs. NRS pain scores, both at rest and during maximal active knee flexion, were verbally reported by the patient and recorded by the nurses 4 times daily. Patient-controlled analgesia using morphine was administered for at least 3 days. A standardized multimodal analgesic regimen, consisting of 50 mg of pregabalin at night, 1 g of paracetamol 4 times daily, and 200 mg of celecoxib twice daily, was prescribed for 5 days.

The quality of recovery from surgery and anesthesia was measured on postoperative day 1 (POD1) using the Quality of Recovery (QoR) Questionnaire[20]. The glucose concentration was measured twice daily on POD1 and POD2. Perioperative complications, such as gastrointestinal bleeding, were assessed by the surgical team daily. Rehabilitation parameters were assessed by a physiotherapist who was also blinded to the group assignments. The knee range of movement and quadriceps power (assessed using the Medical Research Council scale for muscle strength) were assessed on the day of the operation and on the first 3 PODs. The Elderly Mobility Scale (EMS) score was measured on POD1[21]. Walking distance was assessed on the first 3 PODs. Patients who fulfilled the discharge criteria, which included independent walking with or without walking aids, were discharged home around POD5, and the remaining patients were sent to the rehabilitation hospital. Wound and knee conditions were assessed daily during the inpatient stay and at 14 days, 6 weeks, and 3, 6, and 12 months postoperatively in the outpatient clinic for any clinical signs of surgical site infection (SSI), defined using the Centers for Disease Control and Prevention (CDC) guidelines, or periprosthetic joint infection (PJI), defined using the Musculoskeletal Infection Society criteria[22,23].

The primary outcome measure was postoperative pain. A sample size calculation was performed on the basis of NRS pain scores after TKA in a local database, in which the mean pain score (and standard deviation) during maximal active flexion was 5.0 ± 2.8 on POD1. A sample size of 43 per group was found to be sufficient to detect a minimally clinically important difference (MCID) of 2.0 among the 4 treatment groups with 80% power at the 5% significance level. To account for potential dropouts, 45 patients were recruited per group. An adjustment for multiple comparisons was made in all pairwise comparisons to maintain a type-I error rate of <0.05.

Postoperative NRS pain scores were analyzed using the time-weighted average area under the pain-versus-time curve over the first 24, 48, and 72 hours postoperatively (AUC_w). Comparisons of AUC_w pain scores and parametric numeric variables across all 4 groups were performed using analysis of variance (ANOVA), and the Tukey test was used for post-hoc pairwise comparisons. Comparisons of nonparametric numeric variables across all 4 groups were performed using the Kruskal-Wallis test, and the Mann-Whitney U test was used for post-hoc pairwise comparisons. Comparisons of categorical variables

TABLE I Demographics and Operative Data*

Characteristic	Group P (N = 45)	Group IVS (N = 45)	Group PAS (N = 45)	Group IVSPAS (N = 45)
Sex				
Male	12 (27%)	13 (29%)	12 (27%)	16 (36%)
Female	33 (73%)	32 (71%)	33 (73%)	29 (64%)
Age *(yr)*	78.7 ± 7.4	74.9 ± 9.0	74.3 ± 9.3	75.6 ± 7.8
Body weight *(kg)*	67.2 ± 13.3	68.8 ± 11.9	67.4 ±15.9	67.0 ± 12.7
Mechanical tibiofemoral angle *(deg)*	11.8 ± 7.1	9.5 ± 4.7	10.9 ± 5.9	11.5 ± 8.6
Side of TKA				
Right	24 (53%)	24 (53%)	14 (31%)	21 (47%)
Left	21 (47%)	21 (47%)	31 (69%)	24 (53%)
Duration of anesthesia *(min)*	123.6 ± 34.3	127.4 ± 32.4	128.4 ± 43.7	125.3 ± 32.3
Duration of surgery *(min)*	85.6 ± 22.3	94.8 ± 37.0	92.3 ± 40.8	90.7 ± 30.2
Intraoperative blood loss *(mL)*	100 [50-160]	100 [50-175]	100 [50-150]	65 [50-200]
Tourniquet time *(min)*	42.2 ± 28.4	43.9 ± 31.3	47.0 ± 25.8	41.3 ± 23.4

*The values are given as the count with the percentage in parentheses, the mean ± standard deviation, or the median with the interquartile range in brackets. P = placebo, IVS = intravenous corticosteroids, PAS = periarticular corticosteroids, IVSPAS = intravenous + periarticular corticosteroids.

TABLE II Postoperative NRS Pain Scores and Morphine Consumption*

Outcome	Group P (N = 45)	Group IVS (N = 44)	Group PAS (N = 44)	Group IVSPAS (N = 45)	P Value†
Pain score at rest					
Preop.	2.2 ± 2.4	1.7 ± 2.3	2.2 ± 2.6	2.1 ± 2.5	0.760
0-24 hr postop.	2.1 ± 1.8	1.3 ± 1.2†	1.8 ± 1.7	1.3 ± 1.5	**0.026**
0-48 hr postop.	2.2 ± 1.6	1.5 ± 1.3	1.9 ± 1.7	1.3 ± 1.5†	**0.031**
0-72 hr postop.	2.2 ± 1.6	1.6 ± 1.2	1.6 ± 1.4	1.4 ± 1.6†	0.058
Pain score during maximal active knee flexion					
Preop.	6.3 ± 2.0	5.8 ± 2.5	5.8 ± 2.7	6.3 ± 2.0	0.531
0-24 hr postop.	5.0 ± 1.8	3.8 ± 1.7†	4.4 ± 1.8	3.9 ± 2.0†	**0.007**
0-48 hr postop.	5.6 ± 1.5	4.5 ± 1.6†	4.9 ± 1.7	4.3 ± 1.8†	**0.001**
0-72 hr postop.	5.8 ± 1.5	4.8 ± 1.6†	5.0 ± 1.5	4.3 ± 1.7†	**<0.001**
Cumulative morphine consumption *(mg)*					
Through POD2	13 [7.5-19]	6.5 [3-13]†	7 [3.3-13]†	6 [2-10]†	**<0.001**

*The values are given as the mean ± standard deviation or the median with the interquartile range in brackets. Pain scores were calculated as the weighted mean area under the curve. P = placebo, IVS = intravenous corticosteroids, PAS = periarticular corticosteroids, IVSPAS = intravenous + periarticular corticosteroids, POD = postoperative day. †Boldfaced values indicate a significant difference across the 4 study groups. ‡Significantly different from Group P in post-hoc testing.

across all 4 groups were performed using the chi-square test or Fisher exact test, and the same tests were used for the post-hoc comparisons. For the 6 post-hoc pairwise comparisons of nonparametric and categorical variables, the pairwise p values were multiplied by 6 to maintain the probability of false-positive outcomes at <0.05. All statistical analyses were performed using SPSS version 27 (IBM).

Source of Funding
No external funding was received for this study.

Results

The study was conducted between April 2018 and January 2022. A total of 194 patients were approached, 180 were recruited, and 178 were included in the data analysis (Table I). Six of the 194 patients were excluded because of changes in surgical technique; 4, because of hepatitis B infection; 2, because of a history of peptic ulcers; and 2, because they declined to participate. Of the 178 analyzed patients, 45 each were in the P and IVSPAS groups and 44 each were in the IVS and PAS groups; 1 patient in each of the latter groups had died.

TABLE III Pairwise Comparisons of Postoperative NRS Pain Scores and Morphine Consumption*

	Adjusted P Values in Post-Hoc Testing					
	IVSPAS vs. P	IVS vs. P	PAS vs. P	IVSPAS vs. IVS	IVSPAS vs. PAS	IVS vs. PAS
Pain score at rest						
0-24 hr postop.	0.081	**0.048**	0.854	0.996	0.391	0.278
0-48 hr postop.	**0.034**	0.148	0.819	0.934	0.255	0.597
0-72 hr postop.	**0.043**	0.192	0.318	0.908	0.800	0.994
Pain score during maximal active knee flexion						
0-24 hr postop.	**0.023**	**0.010**	0.410	0.991	0.554	0.379
0-48 hr postop.	**0.001**	**0.013**	0.165	0.850	0.269	0.749
0-72 hr postop.	**<0.001**	**0.015**	0.061	0.520	0.230	0.954
Cumulative morphine consumption						
Through POD2	**<0.001**	**0.006**	**0.032**	1.000	1.000	1.000

*Adjusted p values were calculated by multiplying the pairwise p values by 6 to account for the number of post-hoc pairwise comparisons. Boldfaced values indicate a significant difference. P = placebo, IVS = intravenous corticosteroids, PAS = periarticular corticosteroids, IVSPAS = intravenous + periarticular corticosteroids, POD = postoperative day.

The severity of knee deformity in the coronal plane was defined by the mechanical tibiofemoral angle (MTA)[24], with a positive value representing a varus deformity. Patients were followed at 6 weeks and 3, 6, and 12 months postoperatively for wound surveillance.

Pain scores at rest differed significantly across the 4 groups during the first 24 and 48 hours postoperatively ($p = 0.026$ and $p = 0.031$, respectively). Compared with the P group, the pain scores were lower during the first 48 and 72 hours in the IVSPAS group ($p = 0.034$ and $p = 0.043$, respectively) and during the first 24 hours in the IVS group ($p = 0.048$) in the post-hoc comparisons (Tables II and III).

Pain scores during maximal active knee flexion differed significantly across the 4 groups during the first 24, 48, and 72 hours ($p = 0.007$, $p = 0.001$, and $p < 0.001$, respectively). Compared with P group, the pain scores were lower in the IVS and IVSPAS groups during the first 24, 48, and 72 hours ($p \leq 0.023$ for all) (Tables II and III).

Cumulative morphine consumption over the first 2 PODs differed significantly across the 4 groups ($p < 0.001$). Patients in the IVS, PAS, and IVSPAS groups consumed significantly less morphine than those in the P group ($p \leq 0.032$ for all) (Tables II and III). The QoR score differed significantly across the 4 groups ($p < 0.001$). Patients in the IVS and IVSPAS groups had significantly higher scores compared with those in the P group ($p < 0.001$ and $p = 0.032$, respectively) (Tables IV and V).

Active knee flexion differed significantly across the 4 groups on POD3 ($p = 0.020$), with significantly better flexion in the IVSPAS group than in the P group ($p = 0.027$) (Tables IV and V). Quadriceps power differed significantly across the 4 groups on POD2 and POD3 ($p = 0.001$ and 0.012, respectively). Compared with the P group, quadriceps power was greater on POD2 and POD3 in the IVSPAS group ($p = 0.005$ and $p = 0.007$, respectively) and on POD2 in the IVS group ($p = 0.003$) (Tables IV and V).

The postoperative walking distance differed significantly across the 4 groups on the first 3 PODs ($p = 0.004$, $p = 0.001$, and $p < 0.001$, respectively). Compared with patients in the P group, those in the IVSPAS group walked significantly further on the first 3 PODs ($p \leq 0.003$ for all) and those in the IVS and PAS groups walked significantly further on POD2 and POD3 ($p \leq 0.022$ for all) (Tables IV and V). The EMS score differed significantly across the 4 groups ($p = 0.048$). Patients in the IVSPAS group had a higher EMS score than those in the P group ($p = 0.036$), suggesting better mobilization (Tables IV and V).

Compared with the P group, significantly greater glucose levels were found in the IVS and IVSPAS groups at 4, 8,

TABLE IV Postoperative Physical and Hospitalization-Related Parameters*

Outcome	Group P (N = 45)	Group IVS (N = 44)	Group PAS (N = 44)	Group IVSPAS (N = 45)	P Value†
Active knee flexion *(deg)*					
POD1	88.1 ± 12.2	91.1 ± 8.9	87.7 ± 15.5	90.3 ± 9.4	0.451
POD2	86.0 ± 11.5	89.8 ± 14.5	90.6 ± 10.7	91.1 ± 7.1	0.133
POD3	87.8 ± 9.8	89.5 ± 10.3	92.5 ± 10.9	93.6 ± 7.5‡	**0.020**
Muscle power, 0-5 scale					
POD1	3 [3-4]	3 [3-4]	3 [3-4]	4 [3-4]	0.265
POD2	3 [3-3]	4 [3-4]‡	3 [3-4]	4 [3-4]‡	**0.001**
POD3	3 [2.5-3]	3 [3-4]	3 [3-4]	4 [3-4]‡	**0.012**
Walking distance *(m)*					
POD1	19.4 ± 10.6	26.9 ± 13.7	26.6 ± 14.2	30.3 ± 15.7‡	**0.004**
POD2	23.2 ± 13.5	32.3 ± 14.8‡	33.9 ± 17.0‡	34.2 ± 12.3‡	**0.001**
POD3	24.8 ± 13.5	36.8 ± 16.7‡	37.0 ± 16.3‡	43.0 ± 15.7‡	**<0.001**
EMS, 0-10 scale					
POD1	4 [3-6]	4 [3-8.5]	5 [2-8]	6 [4-10]‡	**0.048**
QoR, 0-18 scale					
POD1	14.1 ± 2.2	16.0 ± 2.2‡	15.1 ± 2.2	15.4 ± 2.2‡	**<0.001**
Discharge destination					**0.043**
Home	17 (38%)	24 (55%)	26 (59%)	30 (67%)‡	
Rehabilitation hospital	28 (62%)	20 (45%)	18 (41%)	15 (33%)	

*The values are given as the count with the percentage in parentheses, the mean ± standard deviation, or the median with the interquartile range in brackets. P = placebo, IVS = intravenous corticosteroids, PAS = periarticular corticosteroids, IVSPAS = intravenous + periarticular corticosteroids, POD = postoperative day, EMS = Elderly Mobility Scale, QoR = Quality of Recovery Questionnaire. †Boldfaced values indicate a significant difference across the 4 study groups. ‡Significantly different from Group P in post-hoc testing.

TABLE V Pairwise Comparisons of Physical and Hospitalization-Related Parameters*

	Adjusted P Values in Post-Hoc Testing					
	IVSPAS vs. P	IVS vs. P	PAS vs. P	IVSPAS vs. IVS	IVSPAS vs. PAS	IVS vs. PAS
Active knee flexion						
POD3	**0.027**	0.831	0.103	0.214	0.956	0.485
Muscle power						
POD2	**0.005**	**0.003**	1.000	1.000	0.200	0.122
POD3	**0.007**	0.242	0.973	1.000	0.412	1.000
Walking distance						
POD1	**0.002**	0.063	0.094	0.674	0.644	1.000
POD2	**0.003**	**0.022**	**0.004**	0.932	1.000	0.958
POD3	**<0.001**	**0.003**	**0.002**	0.249	0.286	1.000
EMS						
POD1	**0.036**	1.000	1.000	0.864	0.400	1.000
QoR						
POD1	**0.032**	**<0.001**	0.154	0.541	0.922	0.206
Discharge destination	**0.036**	0.546	0.348	1.000	1.000	1.000

*Adjusted p values were calculated by multiplying the pairwise p values by 6 to account for the number of post-hoc pairwise comparisons. Boldfaced values indicate a significant difference. P = placebo, IVS = intravenous corticosteroids, PAS = periarticular corticosteroids, IVSPAS = intravenous + periarticular corticosteroids, POD = postoperative day, EMS = Elderly Mobility Scale, QoR = Quality of Recovery Questionnaire.

12, and 16 hours after intravenous administration of 16 mg of dexamethasone ($p \leq 0.003$ for all). There were no significant differences beyond 16 hours (Fig. 2).

A significantly higher percentage of patients were discharged home in the IVSPAS group than in the P group ($p = 0.036$) (Tables IV and V). No cases of gastrointestinal bleeding,

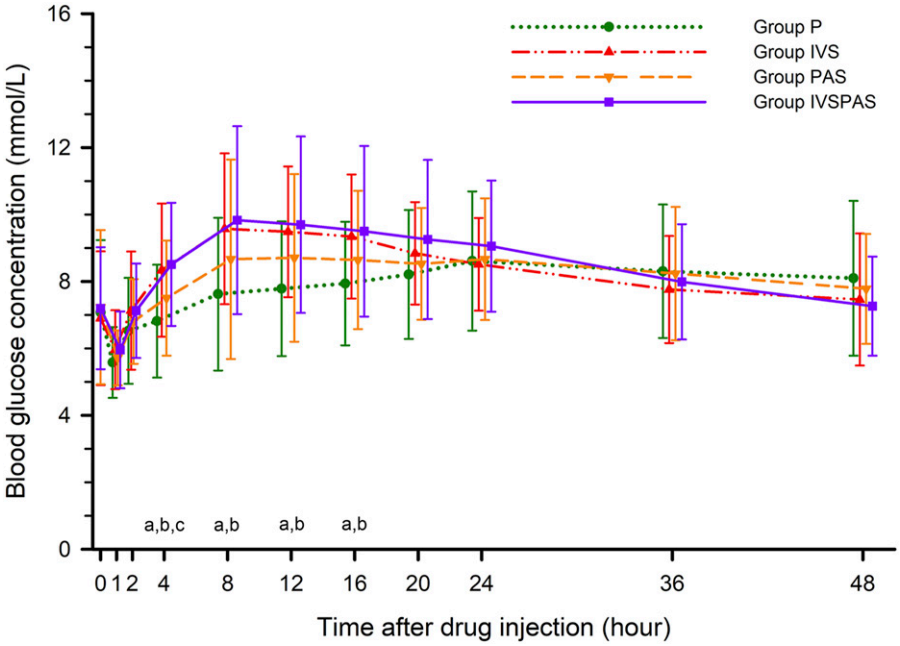

Fig. 2

Mean blood glucose level and standard deviation over time in each group. An "a" indicates that the IVS group (intravenous corticosteroid) was significantly different from the P group (placebo). A "b" indicates that the IVSPAS group (intravenous + periarticular corticosteroid) was significantly different from the P group. A "c" indicates that the IVSPAS group was significantly different from the PAS group (periarticular corticosteroid).

SSI, or PJI were documented during the first 12 months of follow-up.

Discussion

The present study is one of the first RCTs comparing IVS, PAS, and IVSPAS with a placebo control in TKA. The IVS and IVSPAS groups had similar pain relief. Compared with the P group (placebo), the IVSPAS group had significantly better rehabilitation parameters, including active range of knee flexion on POD3, muscle power on POD2 and POD3, walking distance on the first 3 PODs, and EMS and QoR scores on POD1. These improvements in rehabilitation and recovery parameters may have contributed to the higher percentage of patients who were discharged home in the IVSPAS group than in the P group, which has also been found in previous studies[25-28]. IVS was also demonstrated to be superior to placebo in reducing pain. PAS alone was not able to produce a significant reduction in pain, but it yielded a significant improvement in walking distance compared with placebo.

Previous studies have shown the importance of PAS in pain management after TKA[2-12,29-32]. However, the most recent meta-analysis showed that PAS did not provide pain relief and provided minimal improvement in range of knee movement[33]. This conclusion was based on the fact that the reduction in resting pain scores, assessed with a visual analog scale, after TKA was less than the minimal clinically important difference (MCID) of 0.9 point for patients undergoing TKA that was identified by Danoff et al. and Maredupaka et al.[34,35]. The present study also demonstrated that PAS yielded a nonsignificant reduction in pain scores compared with placebo.

The role of IVS in pain management after TKA has been confirmed in meta-analyses, which showed a significant reduction in postoperative pain and morphine consumption[13-16]. The present study also showed that IVS reduced postoperative pain scores and morphine consumption compared with placebo.

The next question is whether the intravenous or periarticular route of corticosteroid administration is better for pain control. To our knowledge, only 2 RCTs have compared both IVS and PAS with placebo[36,37]. Both studies showed that the pain relief provided by IVS and PAS was transient, only reaching significance at 24 hours postoperatively or within the first 24 hours. Furthermore, none of the differences in pain scores relative to placebo exceeded the MCID of 0.9 point for patients undergoing TKA[34,35].

Although the present study failed to directly demonstrate that IVS was better than PAS, it was able to demonstrate that pain scores during maximal knee flexion at 24, 48, and 72 hours were significantly lower in the IVS group compared with the P group, but not in the PAS group compared with the P group. Moreover, the pain score at rest at 24 hours was significantly lower in the IVS group compared with the P group, but not in the PAS group compared with the P group. Therefore, the present study indirectly demonstrated that IVS was superior to PAS in terms of pain reduction and the duration of pain relief.

The final question is whether combining both routes of administration yields additive effects. IVSPAS yielded analgesic effects and functional recovery that were more consistently superior to placebo than was the case with either IVS or PAS group alone, thus indirectly demonstrating superior effectiveness. TKA involves a high surgery-related stress response that can lead to systemic and local inflammatory responses, causing pain, knee swelling, and impaired function[38-40]. IVS exerts analgesic effects by decreasing systemic inflammatory markers and inflammation, leading to pain relief[17,41,42]. PAS decreases local inflammation by reducing inflammatory mediators both locally and systemically[6,10,11] and it also decreases local knee swelling[36,37,39], which results in pain relief. In the present study, the analgesic effect produced by PAS alone was not strong enough to cause significant perioperative pain relief. However, its local analgesic effect involved decreasing local inflammation and knee swelling, which may explain why the number of rehabilitation parameters for the operative knee that were significantly better compared with placebo was larger when PAS was used together with IVS than when either was used alone.

A previous study by our group compared the combination of intravenous dexamethasone and periarticular triamcinolone with intravenous dexamethasone alone[43]. The study was a paired RCT in which all patients undergoing 1-stage bilateral TKA received 16 mg of intravenous dexamethasone. One knee in each patient was randomly assigned to receive LIA with corticosteroid, and the other knee received LIA without corticosteroid. The knee receiving LIA with corticosteroid showed a significantly lower pain score and better range of movement postoperatively. Although the present study showed a similar finding, it was performed in a unilateral TKA setting with a placebo control group, which could be individually compared with the IVS, PAS, and IVSPAS groups. Moreover, the rehabilitation outcomes, including walking distance, EMS and QoR scores, and discharge destination, could be compared between different groups in the present study, whereas the previous study could only compare outcomes between the left and right knees.

Elevated rates of SSI and PJI have been observed in patients receiving long-term treatment with corticosteroids, which have immunosuppressive properties[44]. Thus, the brief use of IVS, PAS, or IVSPAS may also raise concerns for an increased risk of SSI or PJI. However, our study revealed no cases of SSI or PJI with corticosteroid administration.

The present study had certain limitations. The sample size was too small to assess differences in SSI and PJI risks resulting from the different routes of corticosteroid administration. Moreover, measurements of inflammatory markers could be performed to further explain the analgesic effect of different routes of corticosteroid administration.

In conclusion, IVS and IVSPAS were indirectly shown to provide better pain relief than PAS. Although patients in the IVSPAS group had pain relief similar to that in the IVS group, the combination of corticosteroids yielded more significant improvements in the rehabilitation parameters; thus, there was more robust evidence that corticosteroids enhanced functional recovery in the patients who received both periarticular and intravenous corticosteroids than in those who received intravenous corticosteroids only. This study provides new insights into pain management in TKA that may enable

better functional recovery and rehabilitation after TKA, and thereby advance the ability to perform arthroplasty as an outpatient procedure. ■

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Hemiarthroplasty Versus Total Hip Arthroplasty for Femoral Neck Fracture in Elderly Patients

Twelve-Month Risk of Revision and Dislocation in an Instrumental Variable Analysis of Medicare Data

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Background: There is practice variation in the selection of a total hip arthroplasty (THA) or a hemiarthroplasty (HA) for the treatment of displaced femoral neck fractures in elderly patients. Large data sets are needed to compare the rates of rare complications following these procedures. We sought to examine the relationship between surgery type and secondary hip surgery (revision or conversion arthroplasty) at 12 months following the index arthroplasty, and that between surgery type and dislocation at 12 months, among elderly Medicare beneficiaries who underwent THA or HA for a femoral neck fracture, taking into account the potential for selection bias.

Methods: We performed a population-based, retrospective study of elderly (>65 years of age) Medicare beneficiaries who underwent THA or HA following a femoral neck fracture. Two-stage, instrumental variable regression models were applied to nationally representative Medicare medical claims data from 2017 to 2019.

Results: Of the 61,695 elderly patients who met the inclusion criteria, of whom 74.1% were female and 92.2% were non-Hispanic White, 10,268 patients (16.6%) underwent THA and 51,427 (83.4%) underwent HA. The findings from the multivariable, instrumental variable analyses indicated that treatment of displaced femoral neck fractures with THA was associated with a significantly higher risk of dislocation at 12 months compared with treatment with HA (2.9% for the THA group versus 1.9% for the HA group; p = 0.001). There was no significant difference in the likelihood of 12-month revision/conversion between THA and HA.

Conclusions: The use of THA to treat femoral neck fractures in elderly patients is associated with a significantly higher risk of 12-month dislocation, as compared with the use of HA, although the difference may not be clinically important. A low overall rate of dislocation was found in both groups. The risk of revision/conversion at 12 months did not differ between the groups.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Femoral neck fractures represent a major source of morbidity for elderly individuals. By 2050, the global annual incidence is expected to rise to between 7 and 21 million cases owing to an aging population and increased life expectancy[1]. Hip arthroplasty in the form of hemiarthroplasty (HA) or total hip arthroplasty (THA) for the treatment of displaced femoral neck fractures in elderly patients has been established as the standard of care and has been shown to enable rapid mobilization and satisfactory long-term outcomes[2-4].

There is practice variation in the selection of THA versus HA for the treatment of displaced femoral neck fracture in elderly patients[5-7]. Proponents of THA cite evidence of better outcomes associated with THA as compared with HA, such as improved function, quality of life, and implant survival, which have been demonstrated in several randomized controlled trials (RCTs)[8-13]. Advocates of HA point to the association of THA with longer operative time, higher blood loss, and a higher risk of dislocation, without clear evidence of clinically meaningful

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improved function or implant survival, as has been shown in other RCTs[14-17]. Recently, a large, international randomized trial demonstrated no significant differences between THA and HA in the rates of secondary hip procedures at 2 years, although a nonsignificant trend toward higher rates of early revision surgery was identified in the THA group[16].

Given the rarity of certain adverse events such as dislocation and early revision, there may be differences in outcomes between THA and HA that are not easily detected by randomized trials. To detect differences in these rare events, an analysis of large data sets may be helpful. Several recent population-based analyses from outside of the U.S. have investigated the risk of these early adverse events, with conflicting results[18,19]. To our knowledge, no studies of nationally representative data sets that correct for selection bias have been performed on THA versus HA outcomes following femoral neck fractures in the U.S. The purpose of this study was to leverage a large, national data set in order to evaluate the relationship of surgery type, specifically THA versus HA, to the rate of revision or conversion arthroplasties and to the rate of dislocations at 12 months postoperatively among elderly persons undergoing arthroplasty for a displaced femoral neck fracture. We hypothesized that THA would be associated with higher rates of dislocation and revision at 12 months.

Materials and Methods

Study Population and Data Sources

Medicare medical claims data from the Centers for Medicare & Medicaid Services were utilized to identify all fee-for-service beneficiaries with a femoral neck fracture treated with THA or HA during 2017 and 2018. THAs and HAs were identified with use of the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) procedure codes. Femoral neck fractures were identified with use of the following ICD-10-CM diagnostic codes: S72.00XX, S72.01XX, S72.02XX, S72.03XX, S72.04XX, and S72.09XX. To calculate comorbidity, patients were required to have been enrolled in fee-for-service Medicare for ≥12 months prior to surgery. We excluded patients who had arthroplasty for a fracture related to an oncologic or infectious process and those who were undergoing revision or conversion procedures.

Outcome Measures

The key outcomes for this study were secondary hip surgery (revision or conversion arthroplasty) at 12 months following the index arthroplasty and dislocation at 12 months following the index arthroplasty. Patients with THA were classified as undergoing a revision if they had an ICD-10-CM revision code or codes for both implant removal and replacement with laterality matching that of the index arthroplasty, as previously described[20]. Patients with HA were classified as undergoing revision/conversion if they had a code for revision of the femur, codes for removal and replacement of the femur, or a code for replacement of the acetabulum, again with laterality matching that of the index HA[20]. Similar to previously published methodology[21], patients were classified as having a dislocation if there were any of the following ICD-10-CM dislocation codes during the 12 months following the index hip surgery, with matching laterality: T84.02XX and S73.0XXX.

Surgery Type

The primary independent variable of interest was the type of surgery, classified as either THA or HA. Data related to the surgical approach were not available in the Medicare data set and were not included in the analyses. Patients were categorized as having undergone a THA if they had the ICD-10-CM procedure codes 0SR90J9, 0SR90JA, 0SR90JZ, 0SRB0J9, 0SRB0JA, 0SRB0JZ, 0SR9019, 0SR901A, 0SR901Z, 0SR9029, 0SR902A, 0SR902Z, 0SR9039, 0SR903A, 0SR903Z, 0SR9049, 0SR904A, 0SR904Z, 0SRB019, 0SRB01A, 0SRB01Z, 0SRB029, 0SRB02A, 0SRB02Z, 0SRB039, 0SRB03A, 0SRB03Z, 0SRB049, 0SRB04A, or 0SRB04Z. Patients were identified as having undergone an HA if they had the ICD-10-CM procedure codes 0SRR019, 0SRR01A, 0SRR01Z, 0SRR039, 0SRR03A, 0SRR03Z, 0SRR0J9, 0SRR0JA, 0SRR0JZ, 0SRS019, 0SRS01A, 0SRS01Z, 0SRS039, 0SRS03A, 0SRS03Z, 0SRS0J9, 0SRS0JA, or 0SRS0JZ.

Other Covariates

In addition to surgery type, all analyses were adjusted for patient age, sex, race/ethnicity (as listed in the Medicare data set), and low-income status, the latter of which was proxied by dual enrollment in Medicare and in either Medicaid or a state buy-in program. We also included controls for the number of comorbidities, based on Medicare data for the 12 months preceding the index arthroplasty in accordance with the Elixhauser algorithm[22,23], and the U.S. Census Bureau region of the hospital. We included femoral component cement status as a covariate, which was classified as cemented, uncemented, or unspecified on the basis of ICD-10 codes[24].

Statistical Analysis

Our primary goal was to estimate the relationship between surgery type (THA versus HA) and outcomes (revision/conversion and dislocation) at 12 months postoperatively, controlling for potential confounders. One important econometric issue complicated the estimation process: the selection bias regarding the nonrandom "assignment" to surgery type based on differential surgeon-patient decision-making related to variables unobserved in the data set. For example, bone quality, which was unobserved in the data set, might have simultaneously affected the choice of THA versus HA and the probability (conditional on the type of surgery) of adverse outcomes.

We applied the leading statistical method for addressing this type of bias: the 2-stage instrumental variable technique[25-28]. In the first stage of the analysis, the likelihood that a patient would undergo either a THA or HA was estimated with use of a probit specification. Residuals from this first stage, along with surgery type, sociodemographics, and clinical factors included in the first-stage analysis, were included as additional regressors in the revision/conversion and dislocation equations during the second-stage analysis. The resulting estimates of the effect of surgery type on outcomes would be less affected by selection bias.

Instrumental variables are effective only if valid "instruments" are available. Specifically, instrumental variables must be predictive of the type of surgery that a patient underwent but not independently predictive of surgical outcomes, which are conditional on the type of surgery performed. Guided by prior research, we identified 3 instrumental variables as potentially important determinants of a surgeon's choice of surgery: (1) the annual overall volume of THAs (elective procedures and those performed for fractures) at the surgeon's practicing facility, (2) the annual proportion of THAs at the surgeon's practicing facility that were performed for fracture, and (3) the annual proportion of femoral neck fracture cases at the surgeon's practicing facility that were treated with HA[25]. All volume variables were averaged over a 2-year period.

We examined the validity of our proposed instruments with use of the Stock and Staiger test, which was based on the partial r^2 and Chow F statistics for the excluded variables in the first-stage regression analysis[26]. We tested the adequacy of the instruments with respect to whether they could be legitimately excluded from the second-stage outcome estimations that included surgery type and first-stage residuals[27]. In all analyses, standard errors were adjusted to account for potential clustering (i.e., multiple patients within the same hospital).

To provide a sense of the magnitude of the effects, we calculated the predicted probabilities (i.e., adjusted risks) for key variables by varying a specific characteristic (e.g., patient's race, low-income status) while holding all other variables constant at their original levels. These predicted probabilities were calculated at the individual level and then averaged over the entire sample.

All statistical analyses were performed using Stata 16 (StataCorp). The level of significance was set at $p < 0.05$.

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Results

We identified a total of 62,489 elderly (66 to 93 years of age) Fee-for-Service (FFS) Medicare beneficiaries who underwent arthroplasty for a femoral neck fracture during 2017 to 2018 who (1) were enrolled in fee-for-service Medicare at least 12 months prior to their index surgery and (2) were alive and continuously enrolled during the 12-month follow-up period after the index arthroplasty. We excluded 445 patients for unspecified surgery type, 262 patients for missing race/ethnicity or dual enrollment status, and 87 patients for missing Census region. The final sample comprised 61,695 patients, of whom 10,268 (16.6%) received THA and 51,427 (83.4%) received HA.

Patient characteristics are shown in Table I. The HA group was significantly older: 68.5% of patients in the HA group were ≥80 years of age versus 40.5% of patients in the THA group. Compared with patients in the THA group, those in the HA group were more likely to be female (74.5% versus 71.8%; $p < 0.001$), to be of a minority race/ethnicity (8.1% versus 6.4%; $p < 0.001$), to have a higher number of comorbid conditions (mean and standard deviation [SD], 3.4 ± 2.8 versus 2.8 ± 2.6; $p < 0.001$), and to have low income (Medicaid dual enrollment, 13.7% versus 7.7%; $p < 0.001$).

Factors Associated with Surgery Type

Our findings from the multivariable probit model, presented in Table II, indicate that older patients (relative to patients aged 66 to 69 years; the coefficient ranged from −0.23 for patients 70 to 74 years to −1.36 for patients ≥90 years; $p < 0.001$), Black patients (−0.15; $p = 0.001$), patients with low income (−0.33; $p < 0.001$), and patients with a higher comorbidity burden (−0.04; $p < 0.001$) were significantly less likely to undergo THA. In contrast, male patients (0.06; $p < 0.001$) were more likely than female patients to undergo THA.

The predicted probabilities indicated that the likelihood of undergoing THA was 38% for patients aged 66 to 69 years, 29.3% for patients 70 to 74 years, 20.5% for patients 75 to 79 years, 14% for patients 80 to 84 years, 10.1% for patients 85 to 89 years, and 7.4% for patients aged 90 to 93 years. Black patients were less likely than non-Hispanic White patients to undergo THA (13.9% versus 16.7%). Similarly, patients with low income were less likely than patients without low income to undergo THA (11.5% versus 17.3%). Male patients were slightly more likely than female patients to undergo THA (17.4% versus 16.3%).

The 3 candidate instrumental variables performed well as predictors in the first-stage estimation of surgery type ($p < 0.01$). The overall volume of THAs at a facility was associated with an increased likelihood of THA (coefficient, 0.0002; $p = 0.002$), whereas both the proportion of THAs accounted for by fractures (−0.12; $p = 0.006$) and the proportion of fractures treated with HA (−4.03; $p < 0.001$) were associated with a decreased likelihood of THA, even after controlling for sociodemographic and clinical factors[28-30].

Selection-Adjusted Surgery Type and the Risk of Secondary Hip Surgery and Dislocation at 12 Months

In the fully instrumented and adjusted model (Table III), there was no significant difference in the likelihood of revision/conversion within 12 months postoperatively between patients who received THA and those who received HA (coefficient, −0.008; $p = 0.81$; adjusted risk of 2.4% and 2.5%, respectively).

In contrast, patients who underwent THA were significantly more likely than those who underwent HA to experience a dislocation within 12 months (coefficient, 0.17; $p < 0.001$; adjusted risks of 2.9% and 1.9%, respectively). Despite being small in absolute magnitude, these adjusted risks suggest a 53% greater dislocation rate attributable to the type of surgery.

Relative to the youngest group of patients (66 to 69 years of age [adjusted risk 2.7%]), older age was associated with a lower likelihood of experiencing a revision/conversion within 12 months after the index femoral neck surgery (ages 80 to 84: coefficient, −0.18; $p < 0.001$ [adjusted risk, 1.8%]; ages 85 to 89: −0.20; $p < 0.001$ [adjusted risk, 1.5%]; ages ≥90: −0.33; $p < 0.001$ [adjusted risk, 1.2%]). Similarly, Black/African American

TABLE I Characteristics of the Cohort, Overall and by Surgery Type

	Overall (N = 61,695)	THA (N = 10,268)	HA (N = 51,427)	P Value
Age, in years *(no. [%] of patients)*				<0.001
66-69	3,486 (5.7%)	1,427 (13.9%)	2,059 (4.0%)	
70-74	7,457 (12.1%)	2,284 (22.2%)	5,173 (10.1%)	
75-79	11,363 (18.4%)	2,394 (23.3%)	8,969 (17.4%)	
80-84	15,016 (24.3%)	2,090 (20.4%)	12,926 (25.1%)	
85-89	15,605 (25.3%)	1,487 (14.5%)	14,118 (27.5%)	
≥90	8,768 (14.2%)	586 (5.7%)	8,182 (15.9%)	
Sex *(no. [%] of patients)*				<0.001
Female	45,707 (74.1%)	7,372 (71.8%)	38,335 (74.5%)	
Male	15,988 (25.9%)	2,896 (28.2%)	13,092 (25.5%)	
Race/ethnicity *(no. [%] of patients)*				<0.001
Non-Hispanic White	56,860 (92.2%)	9,612 (93.6%)	47,248 (91.9%)	
Black/African American	1,632 (2.6%)	214 (2.1%)	1,418 (2.8%)	
Hispanic	1,715 (2.8%)	230 (2.2%)	1,485 (2.9%)	
Other	1,488 (2.4%)	212 (2.1%)	1,276 (2.5%)	
No. of comorbidities*	3.3 ± 2.8	2.8 ± 2.6	3.4 ± 2.8	<0.001
Low-income status *(no. [%] of patients)*				<0.001
No	53,834 (87.3%)	9,477 (92.3%)	44,357 (86.3%)	
Yes	7,861 (12.7%)	791 (7.7%)	7,070 (13.7%)	
Census region of facility *(no. [%] of patients)*				0.004
Northeast	9,887 (16.0%)	1,646 (16.0%)	8,241 (16.0%)	
South	27,418 (44.4%)	4,536 (44.2%)	22,882 (44.5%)	
Midwest	13,548 (22.0%)	2,148 (20.9%)	11,400 (22.2%)	
West	10,842 (17.6%)	1,938 (18.9%)	8,904 (17.3%)	
Use of cementation *(no. [%] of patients)*				<0.001
No	23,662 (38.4%)	4,848 (47.2%)	18,814 (36.6%)	
Yes	18,742 (30.4%)	1,793 (17.5%)	16,949 (33.0%)	
Unspecified	19,291 (31.3%)	3,627 (35.3%)	15,664 (30.5%)	
Overall facility volume of THAs*	126.7 ± 114.2	149.1 ± 136.2	122.2 ± 108.7	<0.001
Proportion of facility's THAs performed for fractures*	0.35 ± 0.31	0.30 ± 0.20	0.41 ± 0.21	<0.001
Proportion of femoral neck fracture cases treated with HA*	0.82 ± 0.11	0.72 ± 0.22	0.91 ± 0.13	<0.001

*Values given as the mean and standard deviation.

patients (coefficient, −0.25; p = 0.002 [adjusted risk, 2.1%]) and patients of a minority race other than Black or Hispanic (−0.23; p = 0.01; [adjusted risk, 1.8%]) were less likely than non-Hispanic White patients (adjusted risk, 3.2%) to undergo revision/conversion. Male patients (coefficient, 0.11; p < 0.001 [adjusted risk, 2.6% for males versus 2.3% for females]) and patients with a higher number of comorbidities (0.02; p < 0.001) were significantly more likely to experience revision/conversion within 12 months. Finally, cementation was associated with a reduced risk of revision/conversion (1.6% with cementation versus 2.8% without cementation; coefficient, −0.23; p < 0.0001).

In addition to THA surgery type, a higher risk of dislocation was associated with factors such as a higher number of comorbidities (coefficient, 0.03; p < 0.001) and low-income status (0.09; p = 0.01 [adjusted risk, 2.8% versus 1.4%]). Patients of non-Black, non-Hispanic minority races were less likely than non-Hispanic White patients to experience a dislocation (coefficient, −0.21; p = 0.02 [adjusted risk, 1.7% versus 2.3%]). Of note, the use of cement trended toward a significant association with a decreased probability of dislocation (−0.05; p = 0.07 [adjusted risk, 1.8% with cementation versus 2.1% without cementation]).

Tests of the adequacy of the instrumental variables indicated that the proportion of the overall facility volume of THAs performed for fracture and the proportion of femoral neck fracture cases treated with HA were valid instruments, as neither was significantly associated with either outcome. However, the total facility volume of THAs remained a significant predictor

TABLE II Multivariable Regression Coefficient Estimates for Factors Associated with the Choice of THA as the Surgery Type*

	Coefficient	Standard Error	P Value
Age, in years			
66-69	Ref.	—	—
70-74	−0.23	0.028	<0.001
75-79	−0.60	0.027	<0.001
80-84	−0.91	0.027	<0.001
85-89	−1.15	0.028	<0.001
≥90	−1.36	0.033	<0.001
Sex			
Female	Ref.	—	—
Male	0.06	0.015	<0.001
Race/ethnicity			
Non-Hispanic White	Ref.	—	—
Black/African American	−0.15	0.047	0.001
Hispanic	0.008	0.044	0.84
Other	−0.05	0.047	0.31
No. of comorbidities	−0.04	0.003	<0.001
Low-income status			
No	Ref.	—	—
Yes	−0.33	0.024	<0.001
Census region of surgical facility			
Northeast	Ref.	—	—
South	−0.05	0.02	0.02
Midwest	−0.02	0.02	0.30
West	−0.08	0.02	0.001
Candidate instrumental variables			
Overall facility volume of THAs	0.0002	0.00007	0.002
Proportion of facility's THAs performed for fracture	−0.12	0.043	0.006
Proportion of femoral neck fracture cases treated with HA	−4.03	0.054	<0.001

*The dependent variable is a binary indicator given the value of 1 if the patient received a THA and 0 if the patient received HA. The model was estimated with use of a probabilistic probit specification to account for the nonlinear, discrete nature of the dependent variable. The estimation procedure included a constant term and accounted for clustering (i.e., multiple observations within the same facility). The regression coefficients represent the adjusted marginal effect associated with a unit change in the indicator covariate, controlling for all other factors. Positive or negative coefficients indicate a higher or lower likelihood, respectively, of patients receiving THA relative to HA. Given the nonlinearity of the dependent variable, the probit regression coefficients do not represent the magnitude of the effect. To provide a sense of the magnitude of the effect for key factors, we utilized these regression coefficients to calculate the predicted (adjusted) probability of receiving a THA (relative to HA) associated with a 1-unit change in the indicator variable (e.g., Black/African American race), while holding all other factors constant at their actual values. These predicted probabilities are presented in the text.

of outcomes: higher facility case volume reduced the likelihood of dislocation (−0.0004; $p < 0.001$) and revision/conversion (−0.00028; $p = 0.02$).

The recomputed first-stage F statistic, in which total facility volume was treated as a covariate rather than an instrumental variable, indicated that the 2 remaining instruments were highly significant ($F = 13.7$; $p < 0.01$), demonstrating their validity as instrumental variables[31-33].

Discussion

In this nationally representative study of elderly patients undergoing arthroplasty for femoral neck fracture in the U.S., THA was associated with a higher risk of dislocation than HA on instrumental variable analysis, but the overall rates of dislocation were low. There was no significant difference between THA and HA in the adjusted risk of secondary hip arthroplasties (revision or conversion) at 12 months postoperatively. The American Academy of Orthopaedic Surgeons (AAOS) clinical practice guideline describes a possible functional benefit of THA over HA, but at the risk of increased complications[34]; our data are consistent with the reported increased in complication risk as it pertains to dislocation.

The clinical decision to choose HA or THA is multifactorial. Relevant factors include the potential for improved

TABLE III Surgery Type and 12-Month Outcomes: Multivariable, 2-Stage Instrumental Variable Estimation Results*

	Revision/Conversion			Dislocation		
	Coefficient	Standard Error	P Value	Coefficient	Standard Error	P Value
Surgery type: THA (vs. HA)	−0.008	0.033	0.81	0.17	0.03	<0.001
Other key covariates						
Age, in years						
66-69	Ref.	—	—	Ref.	—	—
70-74	−0.03	0.05	0.52	−0.04	0.05	0.46
75-79	−0.09	0.48	0.068	−0.03	0.05	0.55
80-84	−0.18	0.05	<0.001	−0.11	0.05	0.04
85-89	−0.20	0.05	<0.001	−0.06	0.05	0.25
≥90	−0.33	0.06	<0.001	−0.15	0.06	0.01
Sex						
Female	Ref.	—	—	Ref.	—	—
Male	0.11	0.02	<0.001	−0.01	0.03	0.59
Race/ethnicity						
Non-Hispanic White	Ref.	—	—	Ref.	—	—
Black/African American	−0.25	0.08	0.002	−0.13	0.08	0.09
Hispanic	−0.10	0.07	0.16	0.01	0.07	0.85
Other	−0.23	0.09	0.01	−0.21	0.09	0.02
Low-income status						
No	Ref.	—	—	Ref.	—	—
Yes	−0.045	0.04	0.18	0.09	0.03	0.01
No. of comorbidities	0.02	0.004	<0.001	0.03	0.004	<0.001
Cementation	−0.23	0.03	<0.001	−0.05	0.03	0.07
Overall facility volume of THAs	−0.0003	0.0001	0.02	−0.0004	0.0001	<0.001

*For each model, the dependent variable is a binary indicator given the value of 1 if the patient experienced the outcome (e.g., revision/conversion) and given the value of 0 otherwise. Both models also included a constant term and control for the Census region of the surgery facility, an indicator for unspecified cementation, and residuals from the first-stage (choice of surgery type) instrumental variables estimation. The estimation procedure for each outcome accounted for clustering (i.e., multiple observations within the same facility). Both models were estimated using a probabilistic probit specification to account for the nonlinear, binary nature of the dependent variables and the instrumental-variable assumption of the normality of the residuals in each estimation stage. The regression coefficients represent the adjusted marginal effect associated with a unit change in the indicator covariate, controlling for all other factors. Positive or negative coefficients indicate a higher or lower likelihood, respectively, of experiencing the outcome (e.g., revision/conversion within 12 months after the index arthroplasty surgery). Given the nonlinearity of the dependent variables, the probit regression coefficients do not represent the magnitude of the effect. To provide a sense of the magnitude of the effect of our key variable of interest, surgery type, we utilized these regression coefficients to calculate the predicted (adjusted) probability associated with each surgery type (THA versus HA) for each of the 2 outcomes, while holding all other factors constant at their actual values. These predicted probabilities are presented in the text.

functional outcomes with THA and the potential for lower complication risk with HA. In its clinical practice guideline, the AAOS advocates for the "discussion of risk and benefit with patients and families" in the form of "shared decision making."[34] Our results further inform the discussion of risks with precise estimates of the risk of dislocation and revision in a U.S. population. Additionally, our data revealed significant differences in outcomes by age, sex, race, income status, and cement status. We found that advanced age (≥80 years), Black or "other" minority race/ethnicity, female sex, a lower number of comorbidities, and the use of cement were protective against revision/conversion. Additionally, advanced age (80 to 84 years or ≥90 years), "other" race/ethnicity, non-low-income status, and a lower number of comorbidities were protective against dislocation, with use of cement trending toward a significant association with a lower risk of dislocation.

Previous studies have shown conflicting results regarding the comparative revision risks associated with THAs and HAs performed for the treatment of femoral neck fracture. Some relatively small randomized trials[8-13] have shown improved implant survival with THA as compared with HA, but these results have not been consistently reproduced in other randomized trials[14-17]. Notably, a large, international RCT showed no difference in revision rates between the procedures at 2 years postoperatively but did demonstrate a nonsignificant trend toward higher revision rates at 12 months following THA[16]. Meta-analyses of RCTs have shown a lower revision risk at long-term follow-up[31,32] but higher rates of early revision[31]

following THA. A population-based analysis from Canada found no difference in revision rates between the procedures at early or long-term follow-up[18].

Given the uncertainty regarding early revision and the lack of data from population-based data sets in the U.S., we conducted an analysis focused on the risk of revisions/conversions at 12 months following the index arthroplasty with use of a large Medicare data set. Our results showed that THA was not associated with an increased risk of revision/conversion at 12 months. Revisions for acetabular erosion, a known long-term complication of HA, were not reflected in our data.

Historical data have shown a higher risk of dislocation associated with THA, with 3 RCTs from 1986, 1989, and 2000 demonstrating dislocation rates of 12% to 20%[33,35,36]. Meta-analyses that included these studies showed an increased risk of dislocation following THA versus HA[31,32,37]. More recent RCTs showed dislocation rates between 0% to 5% following THAs performed for femoral neck fracture[15,16], and an updated meta-analysis showed no difference in dislocation rates between the 2 procedures[38].

Our data showed a significant difference in dislocation risk between the HA and THA groups, with a dislocation risk of 2.9% following THA and 1.9% following HA. These risks of dislocation are consistent with data from the more recent RCTs showing rates of <5%. Similarly, 2 population-based studies from Canada found dislocation rates of <2% for THA and HA in the treatment of femoral neck fracture[18,39]. Both of these studies demonstrated that THA was associated with an increased risk of dislocation despite the low rates—similar to our own findings[18,39]. In contrast, a population-based analysis from France, in which dual-mobility implants were utilized in 18% of the procedures in the THA group, demonstrated that THA was associated with a reduced risk of dislocation, despite having found a dislocation rate of 5.9% in the THA group[19]. We utilized dislocation and not revision for dislocation as an end point because only a minority of patients with dislocation following arthroplasty for femoral neck fracture undergo revision surgery[40,41].

The limitations of the present study include the use of observational data. It is possible that unobserved variables biased the results, but we attempted to limit this with use of an instrumental variable analysis, as has been done previously in studies of THA versus HA for femoral neck fracture[25]. Second, we were unable to control for surgical approach, implant details including the femoral head size or the use of dual mobility, and body mass index, which may have influenced the rates of dislocation and revision/conversion. Third, we did not report data regarding mortality, quality-of-life outcomes, long-term results, or costs, which are important factors in surgical decision-making. Fourth, we were unable to report the reasons for conversion/revision. Lastly, the majority of the patients in this analysis were non-Hispanic White, which may limit the generalizability of the results; we utilized all of the available cases in the Medicare data set, and thus the racial composition of our cohort reflects the data that were available in the data set.

Conclusions

The findings from this selection-corrected analysis of the type of surgery (HA versus THA) on outcomes demonstrated that the treatment of displaced femoral neck fractures with THA in elderly patients was associated with a significantly increased risk of dislocation at 12 months postoperatively, although the difference may not be clinically important. The overall rate of dislocation was low in both the HA and THA groups. The risk of revision/conversion at 12 months postoperatively did not differ between the groups. ■

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Deep Gluteal Pain Syndrome

Endoscopic Technique and Medium-Term Functional Outcomes

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Background: Sciatic nerve entrapment is an entity that generates disabling pain, mainly when the patient is sitting on the involved side. According to some studies, the presence of fibrovascular bands has been described as the main cause of this pathology, and the sciatic nerve's decompression by endoscopic release has been described as an effective treatment generally associated with a piriformis tenotomy. The aim of this study was to present the medium-term functional results of endoscopic release of the sciatic nerve without resection of the piriformis tendon.

Methods: This prospective, observational study included 57 patients who underwent an endoscopic operation for sciatic nerve entrapment between January 2014 and January 2019. In all cases, a detailed medical history was obtained and a physical examination and a functional evaluation were performed using the modified Harris hip score (mHHS), the 12-item International Hip Outcome Tool (iHOT-12), and the visual analog scale (VAS) for pain. All patients had pelvic radiographs and magnetic resonance imaging (MRI) scans of the hip on the involved side and underwent a prior evaluation by a spine surgeon.

Results: This study included 20 male and 37 female patients with a mean age of 43.6 years (range, 24 to 88 years) and a mean follow-up of 22.7 months. The median mHHS improved from 59 to 85 points. The median iHOT-12 improved from 60 to 85 points. The median VAS decreased from 7 to 2. Postoperative complications occurred in 12% of patients: 1 patient with extensive symptomatic hematoma, 3 patients with hypoesthesia, and 3 patients with dysesthesia.

Conclusions: Endoscopic release of the sciatic nerve by resection of fibrovascular bands without piriformis tenotomy is a technique with good to excellent functional results comparable with those of techniques in the literature incorporating piriformis tenotomy.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Deep gluteal pain syndrome is an entity first described by Robinson in 1947. Classically, its etiology has been attributed to compression of the piriformis tendon, but, because it is a condition that is often underdiagnosed, its real prevalence is unknown. Studies of cadaveric pieces have shown a prevalence ranging from 5% to 17%[1,2]. Currently, the term deep gluteal syndrome is used to characterize the presence of pain caused by extra-pelvic and non-discogenic entrapment of the sciatic nerve, which can occur in any anatomic region of the gluteus[3-9], a concept emerging from the greater knowledge of this pathology, the anatomical variation of entrapment, and the possibility of identifying different etiological agents, such as fibrovascular processes, entrapments at the level of the external rotator complex, vascular anomalies, insertional hamstring disease, or even ischiofemoral impingement[4-10].

Deep gluteal pain syndrome is characterized by the presence of posterior gluteal pain with an inability to sit for >30 minutes, posterior hip pain radiating to the posterior thigh, and paresthesia of the involved limb[1,3-5,8-10]. The physical examination is aimed at performing maneuvers that attempt to reproduce compression of the sciatic nerve, such as the Freiberg test, abduction and external rotation against resistance, activation and stretches of the piriformis, and the seated piriformis stretch test[11,12]. Magnetic resonance imaging (MRI) allows the identification of the sciatic nerve as well as fibrous bands and changes in the normal muscle characteristics, but its usefulness is debatable according to some reports[13]. Electromyography and conduction velocity are complementary tools that make it possible to exclude lumbosacral root disease[14-16]. When dealing with a patient experiencing posterior hip pain, both lumbar spinal pathology and pain referred from the sacroiliac joint should be considered at the time of evaluation and a complementary study of these structures is always necessary[17-21].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H470).

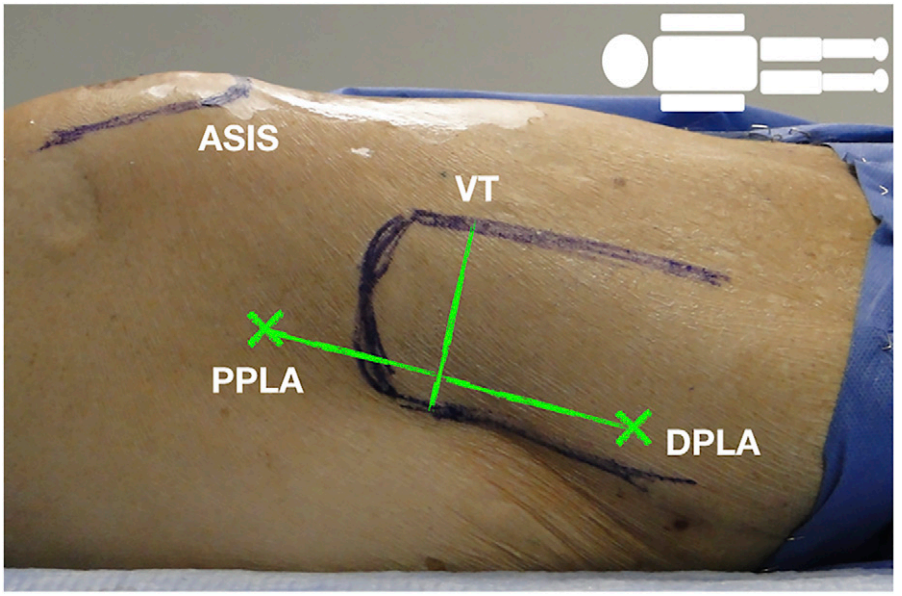

Fig. 1

Location of portals and access to both lateral and subgluteal compartments in a cadaveric study. ASIS = anterior superior iliac spine, VT = vastus tuberosity, PPLA = proximal posterolateral accessory portal, and DPLA = distal posterolateral accessory portal.

Despite the lack of studies and controlled trials that evaluate the effectiveness of surgical management, there have been several reports describing fibrous or fibrovascular formations in the subgluteal area that limit the excursion of the sciatic nerve[9,10,22]. These inflammatory processes that produce fibrovascular bands are often associated with hypertrophic bursae in the peritrochanteric region and a taut iliotibial band with associated pain[17,18,23-26]. The aims of this study were to describe the endoscopic technique developed for the release and exploration of the sciatic nerve in the deep gluteal compartment without piriformis tenotomy and to report the medium-term functional results in the group of patients who underwent this technique.

Materials and Methods

Surgical Technique

With the patient in the supine position and under anesthesia, without traction, and with the limb crossing the surgical field for control and manipulation during the surgical procedure, 2 endoscopic portals are made. The distance between the anterior and posterior borders of the greater trochanter at the level of the vastus tuberosity (VT) is demarcated, and the length of this distance is projected lengthwise in the posterior third of the femur, delineating the proximal posterolateral accessory (PPLA) and distal posterolateral accessory (DPLA) that will be used. The locations of these portals and access to both the lateral and subgluteal compartments, as well as anatomical landmarks and their relationship with the sciatic nerve, were evaluated through a cadaveric study performed by one of the authors of the current investigation (Fig. 1). The first portal, the DPLA portal, is made by incising the skin and opening the iliotibial band and then introducing a blunt trocar to reveal the lateral area using a physiological solution at a constant flow of 0.7 L per minute and pressure of 40 mm Hg per pump. Using endoscopic assistance with 70° optics, the second portal, the PPLA portal, is made by inserting a needle according to the demarcation described above and oriented 60° in the proximal-distal direction and 15° in the posteroanterior direction at the height of the posterior limit of the lateral space and the anterior limit of the deep gluteal space, crossing the aponeurotic junction of the gluteus maximus and the fascia lata. The lateral compartment and the characteristics of the superficial and deep trochanteric bursa are assessed, as well as the septa and/or any extension of a hypertrophic nature, and a wide bursectomy is performed.

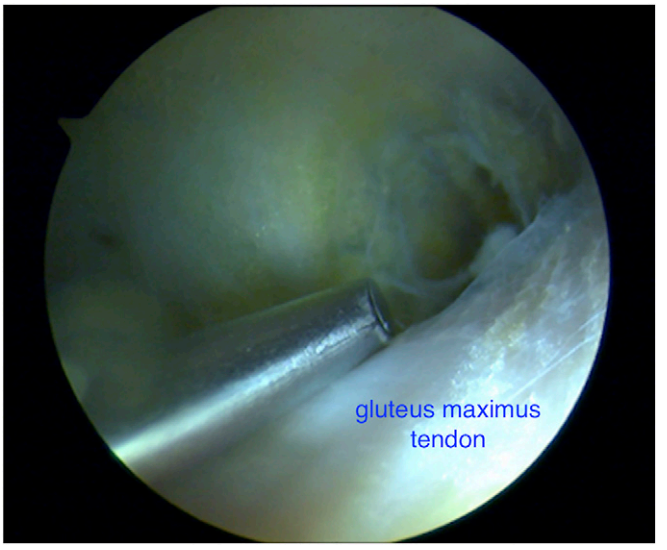

Fig. 2

The insertion of the gluteus maximus tendon is identified as an anatomical landmark to access the deep gluteal space.

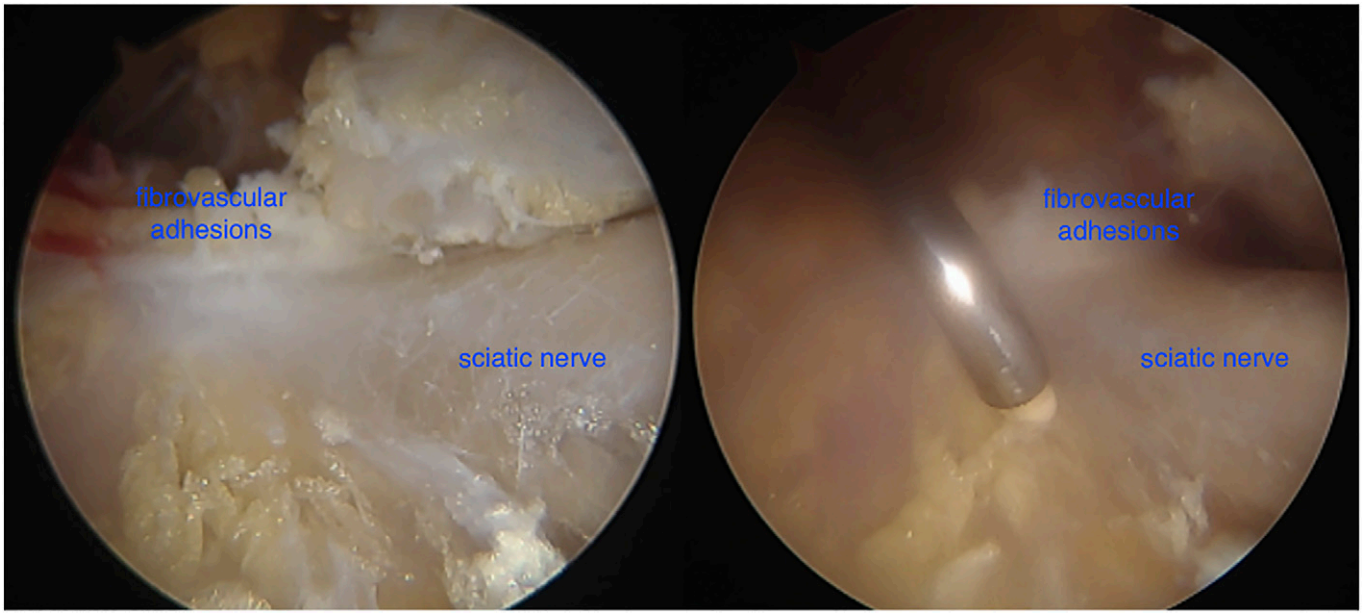

Fig. 3

Left: Presence of fibrovascular bands causing sciatic nerve entrapment. *Right:* Fibrovascular adhesions released with blunt and controlled radiofrequency dissection maneuvers.

Once the examination of the lateral compartment is finished, the insertion of the gluteus maximus tendon is identified, which we consider to be the landmark to access the deep gluteal space (Fig. 2). From this location, the medial femorogluteal bursa is resected using radiofrequency dissection, following the plane formed by the posterolateral aspect of the quadratus femoris muscle. In this procedure, the second surgeon holds the lower extremity and the foot during the surgical procedure, detecting any direct motor stimulation of the nerve or any contiguous stimulation, which may occur within approximately 20 mm of the nerve[27]. If the second surgeon detects movement of the leg, the second surgeon immediately informs the operating surgeon. Once the sciatic nerve has been identified, its adjoining fibrovascular adhesions are released (Fig. 3) with blunt and controlled radiofrequency dissection maneuvers, performing this procedure from distal to proximal and then to the sciatic notch, with special caution regarding the piriform branch of the inferior gluteal artery, which usually crosses the nerve at this location and can be confused with a fibrovascular band (Fig. 4). As an additional procedure, we verified the relationship of the sciatic nerve to the piriformis tendon, taking care not to damage the vascular branch previously described. This verification is performed through flexion, extension, and rotation maneuvers of the hip, observing the free excursion of the sciatic nerve and using a palpator to pull the portion of the piriformis tendon in contact with the sciatic nerve. Finally, free mobilization of the nerve is assessed and the epineural circulation is observed (Fig. 5). Once this objective has been achieved, the procedure is concluded by removing the instruments, evacuating the remaining liquid from the virtual space, and closing the portals.

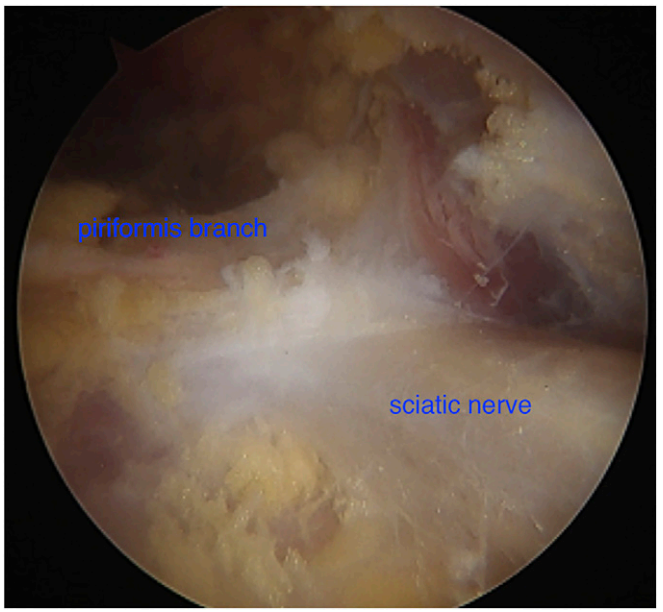

Fig. 4

The piriformis branch of the inferior gluteal artery, which often crosses the nerve at this location. This branch requires special caution when involved in a radiofrequency bursal resection.

Study Patients

In this prospective, observational study, a group of patients who were diagnosed with deep gluteal pain syndrome underwent an operation, between January 2014 and January 2019, performed by the same surgeon, using an endoscopic technique. There were 57 patients who met the inclusion criteria and were recruited for the surgical procedure. The inclusion criteria were

non-discogenic posterior sciatic pain radiating to the posterior thigh and paresthesia; an inability to sit on the involved side due to poorly defined pain, which, in some cases, was associated with paresthesia on the back of the thigh and subsided with a change of position; a pain duration of >6 months; and an inadequate response to conservative treatment. The surgery exclusion criteria used were a diagnosis of lumbosacral pathology, concomitant femoroacetabular impingement, hip osteoarthritis, and diagnosed ischiofemoral syndrome and/or associated gluteus medius tendon detachment. In all cases, a detailed clinical history, physical examination, and functional evaluation using the modified Harris hip score (mHHS), 12-item International Hip Outcome Tool (iHOT-12), and visual analog scale (VAS) for pain were obtained. Pelvic radiographs and hip MRI scans of the involved side were made in all patients. In addition, all patients underwent a prior evaluation by a spinal surgeon and/or a neurosurgeon that included an imaging study and corresponding electromyography, to rule out lumbosacral pathology. All patients provided written informed consent. Clinical evaluation was performed and outcome scores (mHHS, iHOT-12, and VAS) were assessed on the first postoperative day and then at 3 months and at the end of the follow-up period.

Statistical Analysis

Statistical analysis was conducted using SPSS (version 23.0; IBM). Normality was assessed with the Kolmogorov-Smirnov test, which indicated that all of the variables exhibited a nonparametric distribution. The Wilcoxon rank-sum test was therefore used to assess differences between the paired preoperative and postoperative values. The necessary sample size was calculated as 28 using G*Power (version 3.1.9.2; University of Dusseldorf) on the basis of statistical power of 80%, an alpha error of 0.05, a moderate estimated effect size (0.5), and a Wilcoxon test of the difference between groups of paired samples.

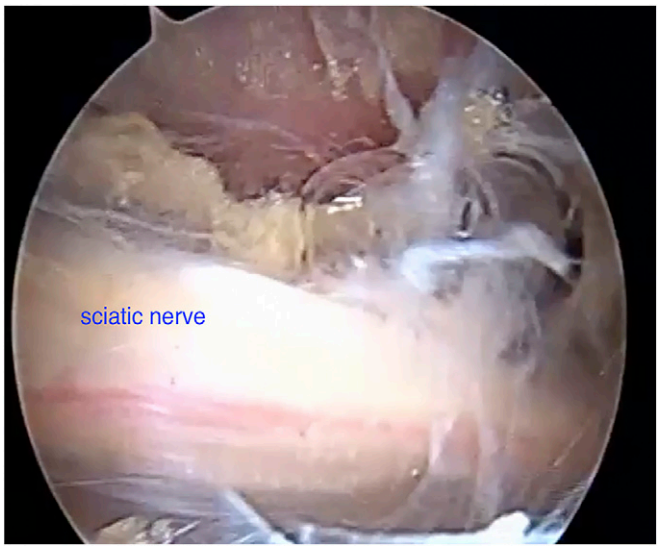

Fig. 5

Sciatic nerve after release. Epineural circulation is observed.

TABLE I Demographic Characteristics

No. of patients	57
No. of hips	57
Female sex	65%
Body mass index* *(kg/m²)*	26.7 (21.2 to 42.7)
Age* *(yr)*	43.6 (24 to 88)
Follow-up* *(mo)*	22.7 (12 to 44)

*The values are given as the mean, with the range in parentheses.

Source of Funding

There was no outside source of funding for this study.

Results

The 57 patients undergoing sciatic nerve release who met the inclusion criteria were evaluated. There were no patients with piriformis compression in this series. The mean age at the time of the surgical procedure was 43.6 years (range, 24 to 88 years), and the mean follow-up was 22.7 months (range, 12 to 44 months). Demographic data are presented in Table I.

The median mHHS improved from 59 points (interquartile range [IQR], 55, 76 points) preoperatively to 85 points (IQR, 79, 88 points) at the latest follow-up ($p < 0.01$) (Fig. 6, Table II). This difference was maintained when separating the groups by sex ($p < 0.01$) (Table III). Based on the mHHS, 17% had excellent results (≥90 points), 53% had good results (80 to 89 points), 28% had fair results (70 to 79 points), and 2% had poor results (<70 points) (Fig. 7). The median iHOT-12 score also improved from 60 points (IQR, 50, 70 points) preoperatively to 85 points (IQR, 80, 95 points) at the latest follow-up ($p < 0.01$) (Fig. 8, Table II). There was a significant improvement ($p < 0.01$) in the median VAS score in the total sample from 7 (IQR, 7, 8) preoperatively to 2 (IQR, 1, 2) postoperatively (Fig. 9, Table II). There were no differences in VAS improvement between patients who had a final follow-up of 12 to 24, 24 to 36, and 36 to 44 months (Fig. 10). At the end of the follow-up period, 19% of the patients reported a VAS score of 0. When separating the groups by sex, this significant improvement was maintained ($p < 0.01$) (Table III).

The following complications took place. An 88-year-old patient with an extensive symptomatic hematoma required selective embolization of the inferior gluteal artery. Three male patients (34, 43, and 45 years of age) presented with hypoesthesia in the gluteal posteroinferior sensory area that resolved between 6 and 12 weeks. Three patients (45, 46, and 54 years of age), 2 of whom were male, presented with dysesthesia that subsided between 4 and 12 weeks postoperatively. Two of these patients had an mHHS of 69 and 77 points at the end of the follow-up period. One patient who did not exhibit neurological alterations or identifiable complications had an mHHS of 78 points at the end of the follow-up period.

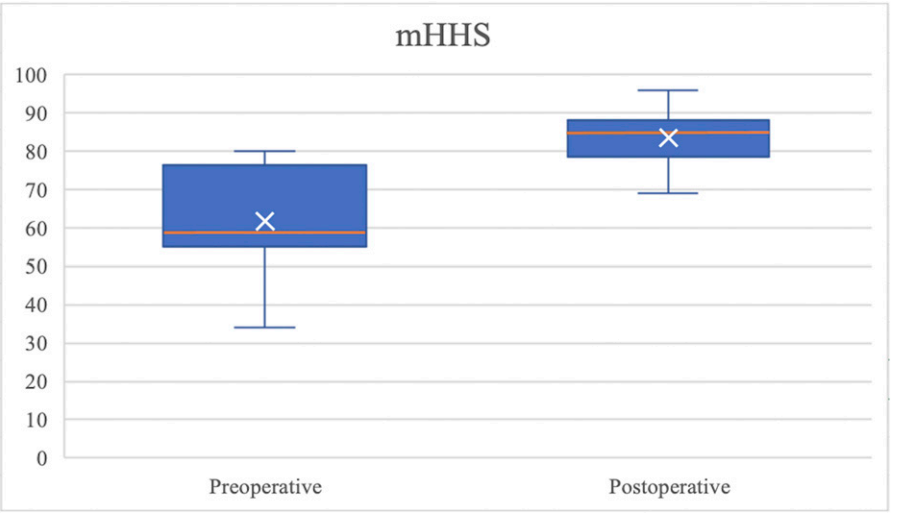

Fig. 6

The median mHHS was 59 points (IQR, 55, 76 points) preoperatively and 85 points (IQR, 79, 88 points) postoperatively. The x indicates the mean, the orange bar indicates the median, the box indicates the IQR, and the whiskers indicate the range.

Discussion

There is currently consensus that deep gluteal pain syndrome is caused by the entrapment of the sciatic nerve in the subgluteal space[28,29], with the presence of fibrovascular bands being relevant in its etiology, according to various reports[4,9,10,22]. This syndrome has an important association with peritrochanteric inflammatory pathology, especially if we consider the repetitive microtrauma that can be caused by the tensor fasciae latae, the gluteus maximus, and the iliotibial band on the greater trochanter and the adjacent bursa, so we believe that it is necessary to consider both compartments together to achieve an optimal result and avoid recurrences[23,25].

We observed a recovery of the excursion of the sciatic nerve after the resection of these fibrovascular bands in 100% of the patients studied. In our experience, this surgical option is the best treatment of this pathology, in contrast to the literature that has described routine resection of the piriformis muscle[6,7,9,12,30-32]. The prevalence of anatomical variants of the piriformis muscle in our study did not differ from that estimated for the general population[22], suggesting that anatomical variants do not explain the chronic symptoms of this condition. Consequently, we consider that the morphological variants would not be the only causes in the pathogenesis of this syndrome.

Piriformis microtrauma can trigger a chronic inflammatory process that eventually results in the development of fibrovascular bands extending up from the piriformis bursa. The same can happen with the external rotator complex. In our experience, a thorough bursectomy associated with band resection yields complete excursion of the nerve without the need for additional procedures. Previous studies have indicated that fibrovascular bands are present in 45% to 100% of cases of deep gluteal pain syndrome and that bursectomy and release of these bands, using one of the several described techniques, should be performed[6-10,22]. Consequently, we do not perform additional surgery on structures that we do not believe are involved in the etiology of the condition, in order to minimize the possibility of postoperative fibrosis. The literature contains

TABLE II Preoperative and Postoperative Outcome Scores*

Test	Preoperative Score*	Postoperative Score*	P Value
mHHS *(points)*	59 (55, 76)	85 (79, 88)	<0.01†
iHOT-12 *(points)*	60 (50, 70)	85 (80, 95)	<0.01†
VAS	7 (7, 8)	2 (1, 2)	<0.01†

*The values are given as the median, with the IQR in parentheses.
†Significant.

TABLE III Preoperative and Postoperative Outcome Scores According to Sex

Test	Preoperative Score*	Postoperative Score*	P Value
mHHS *(points)*			
Male	60 (46, 78)	85 (79, 89)	<0.01†
Female	58 (55, 71)	83 (79, 88)	<0.01†
iHOT-12 *(points)*			
Male	60 (50, 80)	90 (80, 95)	<0.01†
Female	60 (50, 70)	85 (80, 90)	<0.01†
VAS			
Male	7 (7, 8)	2 (1, 2)	<0.01†
Female	7 (7, 8)	2 (1, 2)	<0.01†

*The values are given as the median, with the IQR in parentheses.
†Significant.

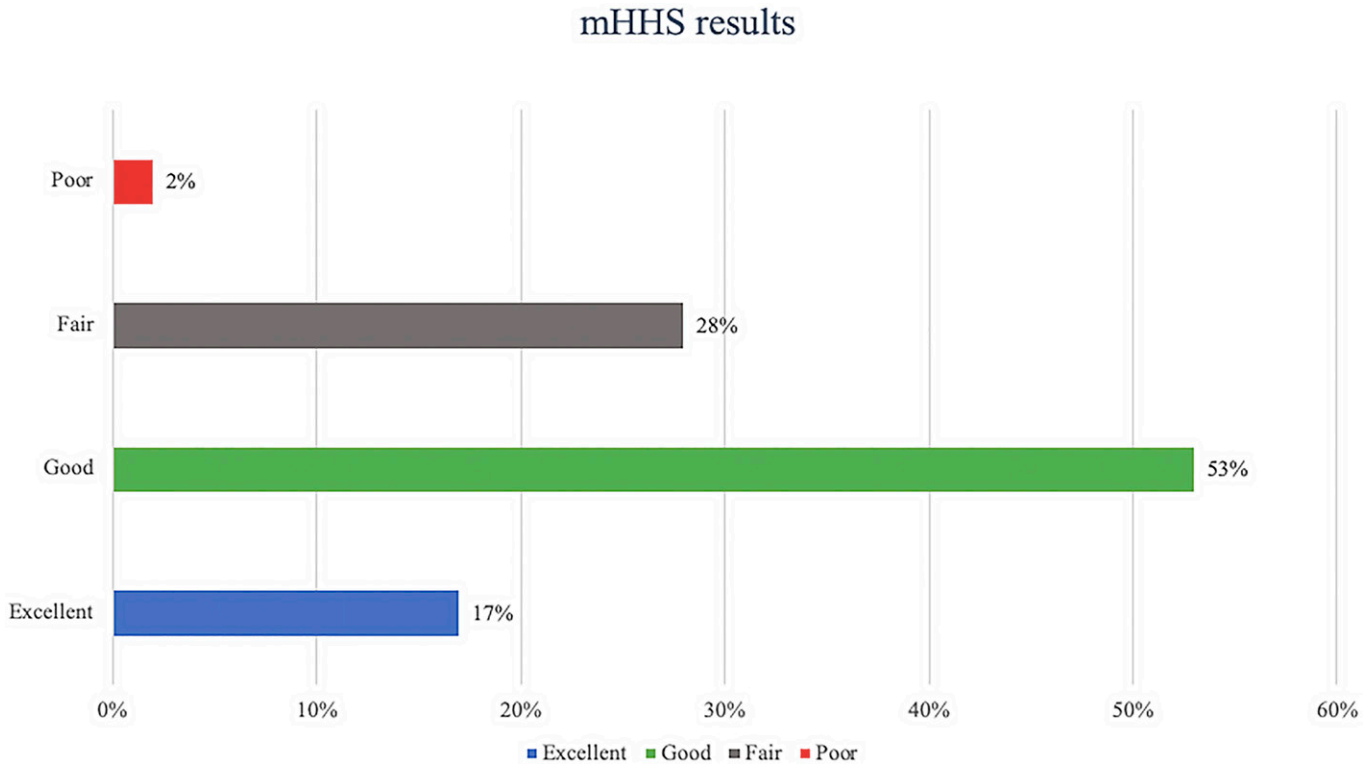

Fig. 7
The distribution of mHHS results.

descriptions of recurrence of symptoms after open surgery, although they are generally based on anecdotes and personal, general estimates, rather than on objective, published data[4]. In any case, we believe that open procedures could be one of the factors directly related to such recurrences, through the generation of a major inflammatory response.

According to various reports, endoscopic decompression of the sciatic nerve by the resection of fibrovascular bands is generally associated with surgical procedures on the piriformis tendon. Martin et al.[6] described a series of 35 patients who underwent endoscopic operations and had a decrease in the VAS pain score from 6.9 to 2.4 and an improvement in the mHHS

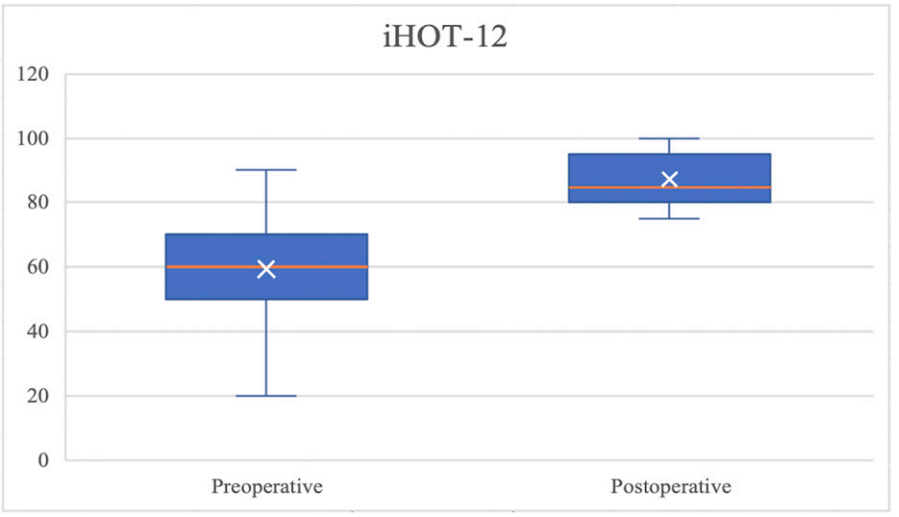

Fig. 8
The median iHOT-12 was 60 points (IQR, 50, 70 points) preoperatively and 85 points (IQR, 80, 95 points) postoperatively. The x indicates the mean, the orange bar indicates the median, the box indicates the IQR, and the whiskers indicate the range.

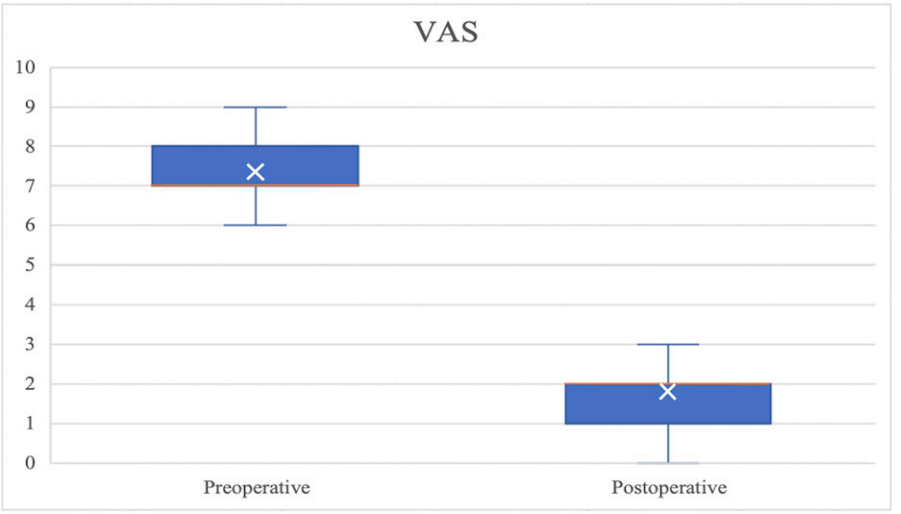

Fig. 9

The median VAS score was 7 (IQR, 7, 8) preoperatively and 2 (IQR, 1, 2) postoperatively. The x indicates the mean, the orange bar indicates the median, the box indicates the IQR, and the whiskers indicate the range.

from 54.4 to 78 points, with excellent to good results in 70% of patients with a mean follow-up of 12 months. Ilizaliturri et al. reported on 15 patients, with a mean follow-up of 30 months, who underwent endoscopic exploration of the sciatic nerve with release of the fibrovascular bands, associated with the release of the piriformis tendon; they described an improvement in the mHHS of 46.8 to 84.9 points and in the VAS score from 7.4 to 1.8[30]. Moreover, Ham et al. presented 24 cases with a mean 32-month follow-up, describing the release of fibrovascular bands and the piriformis, the internal obturator, or the quadriceps

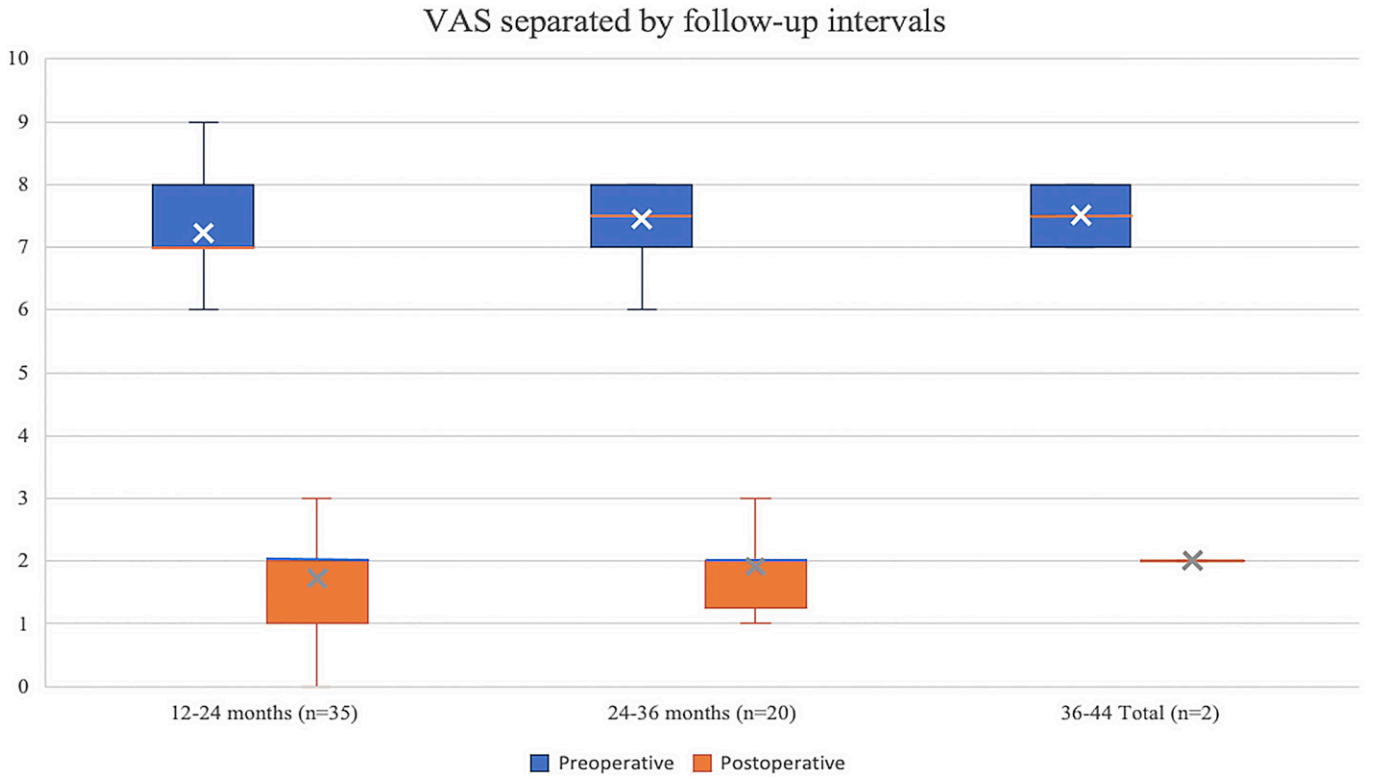

Fig. 10

The mean improvement in the VAS score according to the time until the final follow-up evaluation. The x indicates the mean, the orange bar indicates the median, the box indicates the IQR, and the whiskers indicate the range.

femoris muscle according to the location at which excursion of the sciatic nerve was compromised. The VAS score decreased from 7.1 to 2.5, and the mHHS increased from 59.4 to 85 points, with 87% of cases having no reported complications[31]. Park et al. presented a series of 45 idiopathic cases and 25 posttraumatic cases; the mHHS improved from 61.5 to 84.1 points in the trauma group and from 73.8 to 94.4 points in the idiopathic group[32].

Three branches of the inferior gluteal artery (1 superficial branch and 2 distal deep branches) are currently recognized as representing the main anastomotic tributaries of the medial circumflex femoral artery, which contributes most of the blood supply to the femoral head, in most individuals. The trajectory of the superficial arterial branch is such that its resection is necessary during a tenotomy of the piriformis muscle[33-37].

Kalhor et al.[34] observed that, in some cadaveric preparations, either the deep distal branch (in 5 of 32 preparations) or the superficial branch (in 1 preparation) was the main arterial branch supplying the femoral head, and the medial circumflex femoral artery was an anastomotic tributary of it, and Grose et al. made similar observations[35]. Although there have been no reports of osteonecrosis as a consequence of piriformis tenotomy, those studies provide objective data that support our practice of not resecting this tendon. Finally, epineurolysis of the sciatic nerve under endoscopic magnification requires additional studies. According to our observations, the release of fibrovascular bands combined with epineurolysis may have poor results. Only 3 patients who underwent this procedure had an mHHS of <79 points at the end of the follow-up period.

We present our own technique with the use of modified portals that differ from the classic portal sites proposed in the literature[6,7,30,32,38]. These allow wide access to the peritrochanteric and deep gluteal space and the management of pathologies in both compartments. However, this technique has certain limitations. It requires a subspecialist who is trained and experienced in arthroscopic procedures, because endoscopic triangulation is difficult when performed in a virtual space consisting of soft tissues. In addition, it may be difficult to perform endoscopic repair using our procedure in patients with associated ruptures of the gluteus medius tendon, which would require the use of a third portal.

There were some limitations to this study. We did not include all patients with ill-defined posterior hip pain. We included only patients in our registry of surgical patients, and, therefore, we were unable to provide an estimate of the number of patients who did not meet the criteria for the surgical procedure. We did not have a control group because, based on previous studies and our study, we believe that there is a known benefit of resection of fibrovascular bands and that the cause of treatment failure occurs when this procedure is not performed[6]. Finally, even though the mean follow-up time was 22.7 months (range, 12 to 44 months), we believe that longer-term follow-up will be needed to evaluate our results.

To our knowledge, this is the largest reported series of endoscopic procedures to treat deep gluteal pain syndrome, and its sample size was large enough to achieve statistical power. In addition, excluding cases with intra-articular pathology of the hip and/or spine, and thus including only patients with isolated deep gluteal pain syndrome, has allowed us to more accurately assess the results of our endoscopic procedure. Because there is no gold standard for the diagnosis and treatment of this entity, it is important to point out that the results are similar to those of another case series described in the literature in which piriformis muscle tenotomy was performed. This allows us to consider the possibility that endoscopic management with resection of fibrovascular bands (without the piriformis tenotomy, unlike the technique described by Martin et al.[6]) is the treatment of choice for the management of this pathology.

In conclusion, our endoscopic technique using modified portals allows the release of the sciatic nerve through the resection of fibrovascular bands without performing a piriformis tenotomy. It is a procedure with good to excellent results in the medium term, restoring the functionality of patients regardless of sex and age. ■

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A commentary by James C. Krieg, MD, is linked to the online version of this article.

Conversion to Arthroplasty After Internal Fixation of Nondisplaced Femoral Neck Fractures

Results from a Swedish Register Cohort of 5,428 Individuals 60 Years of Age or Older

Johan Lagergren, MD, Sebastian Mukka, MD, PhD, Olof Wolf, MD, PhD, Emma Nauclér, PhD, Michael Möller, MD, PhD, and Cecilia Rogmark, MD, PhD

Background: Although most nondisplaced or minimally displaced femoral neck fractures are routinely treated with internal fixation, high rates of secondary surgical procedures are common, especially in the elderly population. Primary arthroplasty in elderly patients has been proposed as an alternative treatment to reduce the need for a secondary surgical procedure. The objective of this study was to describe the rate of conversion to arthroplasty within 5 years after internal fixation of nondisplaced femoral neck fractures in patients ≥60 years of age.

Methods: In this observational cohort study of prospectively collected data from the Swedish Fracture Register (SFR) between 2012 and 2018, cross-matched with the Swedish Arthroplasty Register (SAR), 5,428 nondisplaced femoral neck fractures in patients ≥60 years of age were included. Competing risk analysis was used to estimate conversion rates to arthroplasty and mortality in various age groups at 1, 2, and 5 years.

Results: The cumulative incidence function (CIF) for conversion to arthroplasty was 6.3% at 1 year, 8.1% at 2 years, and 10.1% at 5 years. The conversion rates within 2 years were 6.5% in 60 to 69-year-olds, 9.6% in 70 to 79-year-olds, and 7.8% in ≥80-year-olds. Women had a higher risk of conversion; the hazard ratio (HR) was 1.49 (95% confidence interval [CI], 1.19 to 1.87). The cumulative mortality was 21.3% (95% CI, 20.3% to 22.5%) at 1 year, 31.3% (95% CI, 30.0% to 32.6%) at 2 years, and 54.9% (95% CI, 53.1% to 56.7%) at 5 years. Mortality was higher in men at all time points, and the adjusted 1-year HR was 1.79 (95% CI, 1.61 to 2.00).

Conclusions: One in 10 patients ≥60 years of age treated with internal fixation for a nondisplaced femoral neck fracture underwent conversion to arthroplasty within 5 years, and more than one-half of the conversions occurred within the first year. The risk of conversion was highest in women and in patients 70 to 79 years of age. These data warrant further studies in this frail patient group to identify subgroups of patients who would benefit from primary arthroplasty for nondisplaced femoral neck fractures.

Level of Evidence: Prognostic Level III. See Instructions for Authors for a complete description of levels of evidence.

Nondisplaced or minimally displaced femoral neck fractures are commonly treated with internal fixation, because of its less invasive and less time-consuming nature, as well its retention of the biological properties of the hip. Internal fixation with screws or pins is the current clinical routine in Sweden. However, the authors of some recent studies in elderly patients have suggested that the use of hip arthroplasty, rather than internal fixation, as the primary treatment for nondisplaced femoral neck fractures has benefits of lower reoperation and mortality rates as well as improved mobility[1-5]. Some countries have implemented primary arthroplasty as the treatment for nondisplaced femoral neck fractures in patients ≥60 years of age. The 2021 annual report of the Australian & New Zealand Hip Fracture Registry showed that approximately 50% of nondisplaced femoral neck fractures were treated with arthroplasty during 2020[6]. In Sweden, internal fixation has

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H376).

been reported to be used in 87% of patients ≥60 years[7] and arthroplasty is used only in selected cases[8]. There is an increasing interest in the degree of posterior tilt[9]. In an informal questionnaire in 2021, a majority of hospitals in Sweden reported that they were also guided by the lateral radiograph when choosing the surgical method (unpublished data). Some hospitals use only parallel screws, some use only parallel hook pins, and some use both. The principles of fixation are the same for both. Biplanar fluoroscopy is used in most but not all hospitals. These variations illustrate the lack of solid scientific evidence regarding the optimal treatment of this common fracture and also the lack of national guidelines in Sweden. As hip fracture surgery is performed in every emergency hospital by a variety of orthopaedic surgeons, we sought to explore the results after internal fixation for nondisplaced femoral neck fractures in contemporary everyday practice.

The objective of this observational study was to describe the conversion rate to arthroplasty within 5 years after internal fixation of nondisplaced femoral neck fractures in patients ≥60 years of age, using a competing-risk analysis with death as a competing event. In addition, we explored the conversion rate in various age groups, as well as risk factors for conversion surgery and mortality.

Materials and Methods

Ethics

Ethical approval was granted from the Central Ethical Review Board in Gothenburg (ref. 830-17) and from the Swedish Ethical Review Authority (diary numbers 2019-05024 and 2022-00972-02).

Study Design

This observational cohort study was based on data derived from the Swedish Fracture Register (SFR) and the Swedish Arthroplasty Register (SAR), following the STROBE (Strengthening The Reporting of OBservational studies in Epidemiology) guidelines[10].

The SFR is a national quality register for the management of fractures and was established in 2011[11,12]. Data on patients and fracture characteristics, injury mechanism, and treatment are recorded online by each affiliated department via a digital form completed by the treating orthopaedic surgeon. The aim is to register the treatment (both operative and nonoperative) of all fractures. Patients with a permanent Swedish personal identification number and a fracture that occurred in Sweden are registered. There is a newer version of fracture classification[13], but when the SFR was established in 2011, it used the OTA/AO 2007 classification system, which was found at the time to have high accuracy and validity as implemented in the register, and has continued using this classification system since then. Therefore, in the current study, we have used the same fracture classification system because it was the version in place when the database began and it has not been updated[14]. During the study period, completeness compared with the National Patient Register (NPR) increased from 18% in 2012 to 54% in 2018 for hip and femoral fractures, due to the stepwise national implementation of the SFR. The completeness for femoral fractures was 83% in 2021, and coverage was 100%, meaning that all orthopaedic departments report to the register. A completeness analysis is performed annually by both the SFR and the SAR, by cross-matching against the NPR[15]. Swedish law mandates that both privately and publicly funded hospitals deliver data to the NPR, and all inpatient hospitals and outpatient visits are included.

In the SFR, femoral neck fractures are classified according to the simplified OTA/AO classification[16] as nondisplaced (31-B1), basicervical (31-B2), or displaced (31-B3), on the basis of an anteroposterior radiograph, which has been shown to have moderate interobserver reliability[17]. The treatment is entered by the treating physician and transformed to its Nordic Medico-Statistical Committee (NOMESCO) Classification of Surgical Procedures (NCSP) procedure code[18]. Internal fixation was defined by NCSP codes in the SFR and was grouped into fixation with pins, screws, a sliding hip device, or other fracture fixation (Table I).

The SAR has an annual completeness of approximately 98% for total hip arthroplasty and 97% for hemiarthroplasty[7], our main outcomes. The SAR contains all diagnoses leading to a hip (or knee) arthroplasty, and thus includes both patients primarily treated with arthroplasty for arthrosis or femoral neck fracture as well as patients undergoing an arthroplasty after the failure of internal fixation. Within the registers and in the linking of registers, patients are identified by their unique personal identity number given to all Swedish citizens. By use of this personal identity number, all secondary surgical procedures and deaths can be linked to the first registered procedure (thus making lifelong follow-up possible, relying on reporting from the Swedish hospitals). The completeness of the SAR for revision surgical procedures was 94% in 2020 and 2021.

TABLE I Characteristics of the 5,428 Patients Treated with Internal Fixation

Characteristic	Values (N = 5,428)
Age* *(yr)*	80.5 ± 8.9
Women†	3,693 (68.0%)
Low-energy trauma†	5,105 (94.0%)
Fall at care facility	
Total†	789 (14.5%)
Age group†	
60 to 69 years (n = 741)	25 (3.4%)
70 to 79 years (n = 1,541)	143 (9.3%)
≥80 years (n = 3,146)	621 (19.7%)
Treatment†	
Hook pins	3,106 (57.2%)
Screws	2,084 (38.4%)
Sliding hip device	145 (2.7%)
Other	93 (1.7%)

*The values are given as the mean and the standard deviation. †The values are given as the number of patients, with the column percentage in parentheses. ‡The values are given as the number of patients, with the row percentage in parentheses.

Both the SFR and the SAR are cross-matched every 24 hours with a national population database, based on the personal identity numbers, to update mortality rates. The mortality dates used in the present study were derived from the SFR.

Patient Selection

This was a registry-based cohort study of patients ≥60 years of age with nondisplaced femoral neck fractures treated with internal fixation who had been prospectively registered in the SFR between January 2012 and December 2018 at the time of the injury. Of 47,487 registered hip fractures, 6,076 were classified as nondisplaced femoral neck fractures (AO/ASIF 31-B1) in patients ≥60 years of age. Exclusion criteria were subsequent ipsilateral or contralateral hip fracture, treatment other than internal fixation, Girdlestone procedure, and erroneous coding or dates (Fig. 1). After exclusion, there were 5,428 patients in the study.

Outcome Measures

The main outcome measure was the conversion rate to arthroplasty after treatment with internal fixation, using a competing-risk model with mortality as the competing event. We also assessed hazard ratios (HRs) for conversion to arthroplasty based on sex and surgeon experience. The variables available for analysis were limited to those collected in the SFR. Age, sex, and surgeon experience were used in the regression analysis for mortality and conversion rates. Surgeon experience was dichotomous and was defined as "surgeon in training," corresponding to a resident, and "specialist," corresponding to a consultant orthopaedic surgeon with finished training.

Confounders

Before the beginning of the study, we decided to include the variables of age, sex, and surgeon experience. These variables have previously demonstrated an association with both the exposure and outcome and are not considered to be in the causal pathway between potential risk factors for conversion to arthroplasty and/or mortality and the outcome.

Statistical Analysis

Patient characteristics were described using counts with proportions and means with standard deviations. A competing-risk model was used to estimate conversion rates, with death as a competing event, as well as mortality rates, utilizing the "cmprsk" package in R version 4.0.2 (The R Foundation for Statistical Computing). The results are presented as the cumulative incidence function (CIF) and 95% confidence interval (CI), expressed as percentages. The mortality risk at 1 year and the reoperation risk at 2 years were analyzed using Cox regression adjusted for age, sex, and surgeon experience. HRs are presented with 95% CIs.

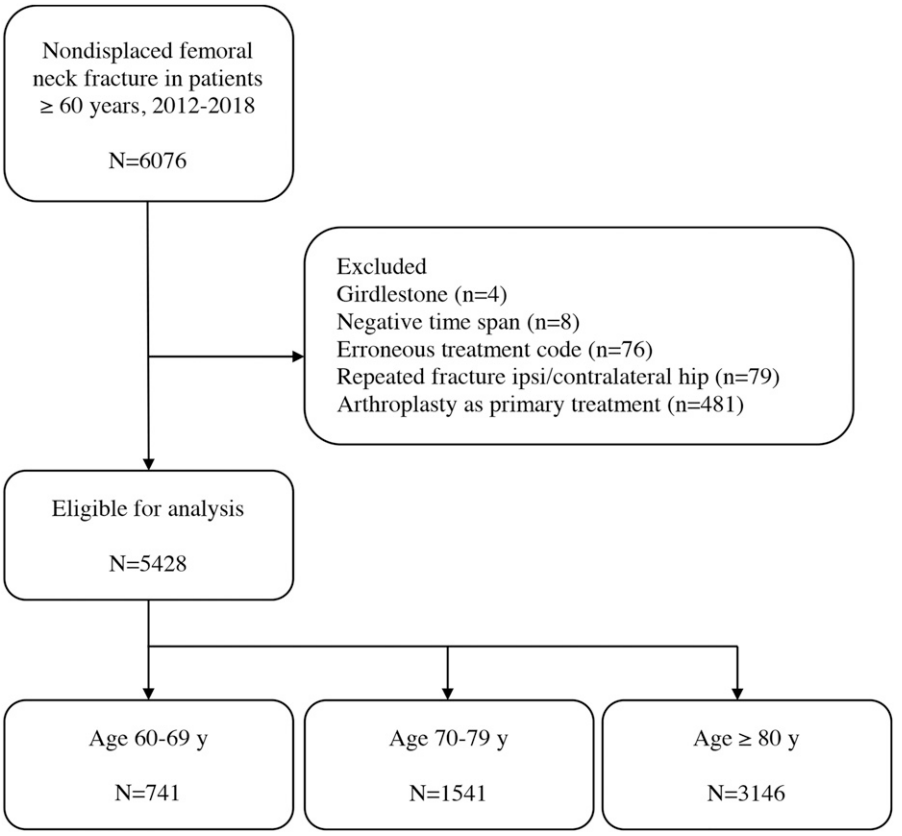

Fig. 1

Flowchart for the study cohort.

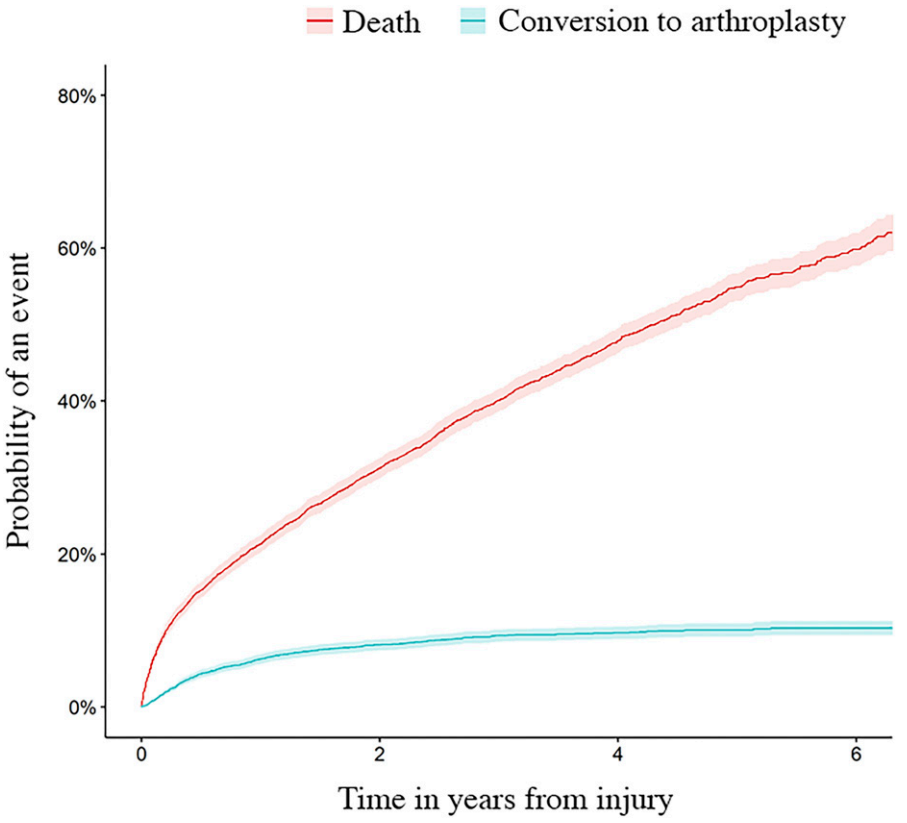

Fig. 2

CIFs from competing-risk modeling of conversion to arthroplasty and death after internal fixation of nondisplaced femoral neck fractures. The shading indicates the 95% CI.

The assumption of proportional hazards was assessed by plotting Schoenfeld residuals.

Source of Funding

Funding was received from the Axel Linders Foundation, an independent trust.

Results

Patients and Descriptive Data

The study cohort included 5,428 patients with a nondisplaced femoral neck fracture (mean age, 81 years; 68% women) registered in the SFR between January 1, 2012, and December 31, 2018. Almost 96% of the nondisplaced femoral neck fractures treated with internal fixation received either hook pins (57.2%) or screws (38.4%) (Table I).

Conversion to Arthroplasty

The estimated CIF for conversion to arthroplasty in the entire cohort was 6.3% (95% CI, 5.7% to 6.9%) at 1 year, 8.1% (95% CI, 7.4% to 8.9%) at 2 years, and 10.1% (95% CI, 9.2% to 11.0%) at 5 years (Fig. 2, Table II).

The CIF at 5 years was 10.0% (95% CI, 7.7% to 12.9%) in 60 to 69-year-olds, 13.0% (95% CI, 10.6% to 15.1%) in 70 to 79-year-olds, and 8.7% (95% CI, 7.7% to 9.8%) in ≥80-year-olds (Fig. 3, Table III). Women had a higher cumulative conversion rate of 14.9% (95% CI, 13.3% to 16.4%), compared with 8.8% (95% CI, 7.1% to 10.5%) for men.

Risk Factors for Conversion to Arthroplasty

Women had a higher risk of conversion compared with men (HR, 1.49 [95% CI, 1.19 to 1.87]). Surgeon experience did not influence the risk of conversion to arthroplasty (HR, 1.1 [95% CI, 0.9 to 1.3]) in a regression model adjusted for age and sex. Patients 70 to 79 years of age also had an increased risk of conversion (HR, 1.5 [95% CI, 1.1 to 2.0]).

TABLE II Conversion to Arthroplasty by Year

Time	No. at Risk	Cumulative Events	CIF*
1 year	3,919	340	6.3% (5.7% to 6.9%)
2 years	2,640	433	8.1% (7.4% to 8.9%)
3 years	1,646	479	9.3% (8.6% to 10.2%)
4 years	935	489	9.7% (8.9% to 10.6%)
5 years	450	496	10.1% (9.2% to 11.0%)

*The values are given as the CIF, with the 95% CI in parentheses.

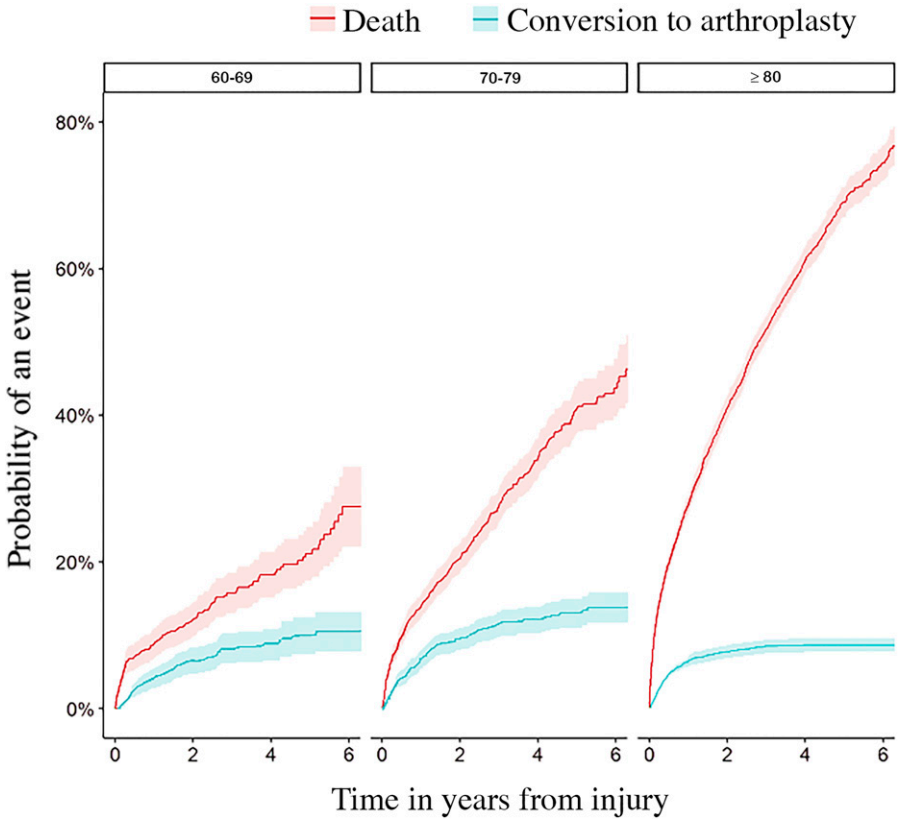

Fig. 3

CIFs from competing-risk modeling of conversion to arthroplasty and death after internal fixation in 3 age groups.

Mortality

Mortality in all patients ≥60 years of age was 21.3% (95% CI, 20.3% to 22.5%) at 1 year, 31.3% (95% CI, 30.0% to 32.6%) at 2 years, and 54.9% (95% CI, 53.1% to 56.7%) at 5 years. Patients ≥80 years of age had the highest mortality rate at all time points (Table IV). Mortality was higher in men at all time points, and their adjusted HR at 1 year was 1.79 (95% CI, 1.61 to 2.00).

Discussion

In this large cohort of patients ≥60 years of age with a nondisplaced femoral neck fracture treated with internal fixation, 1 in 10 had a subsequent hip arthroplasty within 5 years, and more than one-half of the conversions had already occurred by 1 year. The conversion rate to arthroplasty was highest in women and patients who were 70 to 79 years of age.

A failure of internal fixation resulting in the need for a conversion to hip arthroplasty is a severe complication in older patients. Not only does an arthroplasty after fracture fixation failure have an inferior outcome compared with primary hip arthroplasty[19-22], but also the prolonged period of pain and discomfort caused by the complication is detrimental. Selecting arthroplasty as the primary treatment could allow faster mobilization and could potentially decrease morbidity and mortality after the surgical procedure[23], although the difference

TABLE III Conversion to Arthroplasty by Age Group and Time

Age Group and Time	Cumulative Events*	CIF†
60 to 69 years (n = 741)		
1 year	31 (4.2%)	4.2% (3.0% to 5.9%)
2 years	47 (6.3%)	6.5% (4.9% to 8.6%)
5 years	61 (8.2%)	10.0% (7.7% to 12.9%)
70 to 79 years (n = 1,541)		
1 year	104 (6.7%)	6.8% (5.6% to 8.1%)
2 years	144 (9.3%)	9.6% (8.2% to 11.2%)
5 years	174 (11.3%)	13.0% (10.6% to 15.1%)
≥80 years (n = 3,146)		
1 year	205 (6.5%)	6.5% (5.7% to 7.4%)
2 years	242 (7.7%)	7.8% (6.9% to 8.8%)
5 years	261 (8.3%)	8.7% (7.7% to 9.8%)

*The values are given as the number of patients, with the percentage of the group total in parentheses. †The values are given as the CIF, with the 95% CI in parentheses.

TABLE IV Mortality by Age Group and Time

Age Group and Time	Cumulative Events*	CIF†
60 to 69 years (n = 741)		
1 year	66 (8.9%)	8.9% (7.1% to 11.2%)
2 years	88 (11.9%)	12.1% (10.0% to 14.7%)
5 years	124 (16.7%)	21.2% (17.8% to 25.2%)
70 to 79 years (n = 1,541)		
1 year	216 (14.0%)	14.0% (12.4% to 15.9%)
2 years	307 (19.9%)	20.5% (18.6% to 22.7%)
5 years	459 (29.8%)	40.9% (37.6% to 44.5%)
≥80 years (n = 3,146)		
1 year	876 (27.8%)	27.9% (26.3% to 29.5%)
2 years	1,255 (39.9%)	41.0% (39.3% to 42.8%)
5 years	1,738 (55.2%)	69.0% (66.9% to 71.2%)

*The values are given as the number of patients, with the percentage of the group total in parentheses. †The values are given as the CIF, with the 95% CI in parentheses.

in mortality between internal fixation and arthroplasty is not clear in the literature[2,5,24].

Conversion rates of 8% to 16% after internal fixation of nondisplaced femoral neck fractures have been reported in the literature[5]. Our results are in concordance with a recent cohort study including 1,505 patients in which the conversion rate was 10% (7% to total arthroplasty and 3% to hemiarthroplasty) and the total reoperation rate was 17% at a mean follow-up of 3.2 years[20]. However, 20% of patients in a recent randomized controlled trial (RCT)[1] underwent major reoperations within 2 years after internal fixation. The discrepancy in results between observational studies and RCTs has been noted previously[25]. This discrepancy could be explained by the inclusion of healthier and more vital patients in RCTs[26].

Individual radiographs are not available in observational register studies such as the present one. Nondisplaced femoral neck fractures are not uniform; rather, there are subgroups of fracture patterns with different risks of reoperation[7,24,27]. A preoperative posterior tilt of >20° may increase the risk of failure requiring a major reoperation[19,27], and an anterior tilt of >10° may also be associated with a risk of treatment failure requiring a major reoperation[20]. In contrast, occult nondisplaced femoral neck fractures (fractures that are not visible on radiographs but are visualized with magnetic resonance imaging) have low reoperation rates[21]. Differences in inclusion of these subgroups between RCTs and observational studies could contribute to the differences in reported reoperation rates. In addition, the effect of age may be confounded by greater reluctance of elderly individuals to seek health care for complications such as implant failure, osteonecrosis, and nonunion after internal fixation, and greater reluctance of surgeons to treat these complications in individuals who are frailer or have a shorter life expectancy; this has the potential to at least partially account for our finding of lower conversion rates in patients ≥80 years of age.

The type of internal fixation could also affect the rate of conversion to arthroplasty; however, no apparent differences between pins, screws, and sliding hip devices have been reported[28-31]. Two pins or screws were used almost exclusively in this cohort, in accordance with the current clinical practice for internal fixation in Sweden.

An important limitation of the present study was the lack of patient-reported outcomes, which are important in the comparison of internal fixation and arthroplasty. In their RCT, Dolatowski et al. concluded that hemiarthroplasty led to better mobility compared with internal fixation[1]. Their findings suggested that certain elderly patients with a nondisplaced femoral neck fracture may benefit from being treated with a latest-generation hemiarthroplasty rather than internal fixation. This is possibly also true for the subgroups with a dorsal or anterior fracture tilt, which increases the risk of reoperation[20]. However, there is a need for further high-level evidence to evaluate these claims, and large, randomized studies such as SENSE[31], HipSTHeR[32], and FRUITI[33] are ongoing.

The present study had limitations stemming from its register-based design. As mentioned, we did not have radiographs or data on frailty, comorbidities, or cognitive impairment. The unavailability of radiographs eliminated the possibility of assessing fracture displacement, which would have been a major confounder of these results. The other mentioned factors might also have influenced conversion rates and thus introduced a risk of residual confounding.

We chose to focus on conversion to arthroplasty as it is the most common major reoperation to treat failure after internal fixation[5] and the high completeness of the SAR for arthroplasties provided us with reliable data for this outcome. The unique Swedish personal identity number enabled us to link data between the SFR and the SAR and ensured a high completeness of the data used to calculate the conversion rate. However, it is important to note that the results of the present study do not reflect the total complication or reoperation rates after internal fixation. In particular, other types of reoperations such as implant removal, excision arthroplasty, and refixation were not analyzed due to inadequate data sources, and complications and reoperations need not be associated (e.g., a complication may be treated nonoperatively, or routine screw removal may be performed in patients without complications).

In conclusion, using the need for conversion to arthroplasty as a marker of major complications, internal fixation of a nondisplaced femoral neck fracture in patients ≥60 years of age had an acceptable outcome; 9 of 10 patients did not have this type of secondary surgical procedure during a 5-year follow-up. More than one-half of the patients died within 5 years. Most of the conversions took place in the first year, but attention must be paid to late-occurring complications as well. Until large RCTs have compared internal fixation and arthroplasty for patients with a nondisplaced femoral neck fracture in terms of postoperative pain and function, we interpret our result as supporting the current regime in which fixation is the first choice for a majority of patients. Nevertheless, the somewhat

higher risk of conversion in women and in patients who were 70 to 79 years of age underlines the need for studies to further identify subgroups of patients who would benefit from primary arthroplasty for a nondisplaced femoral neck fracture. ■

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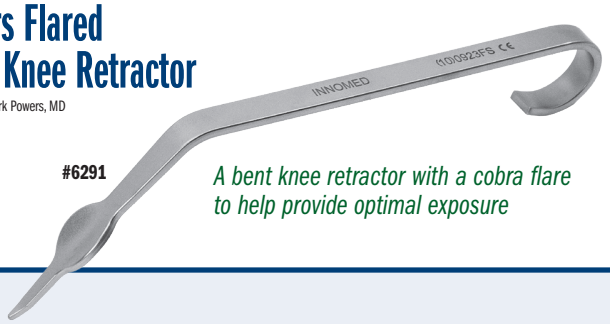

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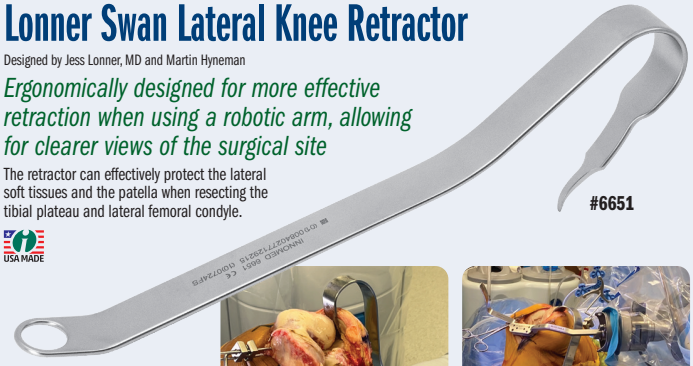

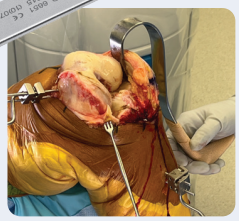

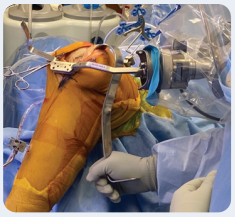

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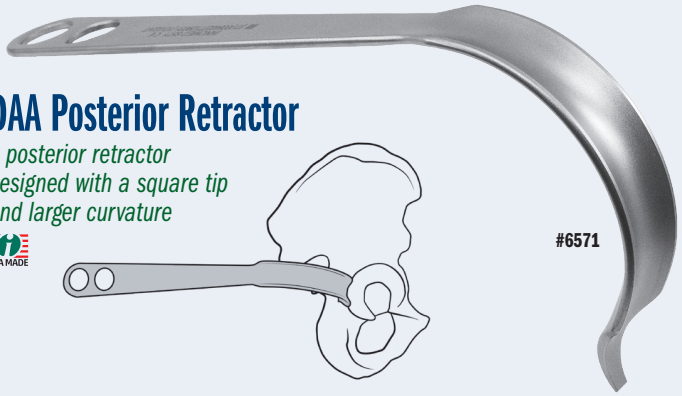

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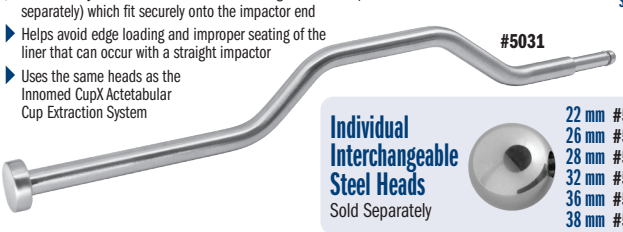

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Comparison of Functional Recovery Between Unicompartmental and Total Knee Arthroplasty

A Randomized Controlled Trial

Boonchana Pongcharoen, MD, Pongsathorn Liengwattanakol, MD, and Krit Boontanapibul, MD

Investigation performed at the Department of Orthopaedic Surgery, Thammasat University, Pathum Thani, Thailand

Background: Comparisons of functional recovery between unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA) using performance-based tests are lacking. Therefore, this study aimed to compare 2-minute walk test (2MWT) and Timed Up-and-Go test (TUG) results between UKA and TKA for isolated medial knee osteoarthritis (OA). We hypothesized that UKA yields faster functional recovery than TKA as measured with the 2MWT and TUG.

Methods: We conducted a randomized controlled trial comparing medial UKA and TKA in patients with isolated medial knee OA. A total of 110 patients were enrolled; after 11 exclusions, 99 patients (50 UKA, 49 TKA) were included in the final analysis. The patients were tested using the 2MWT and TUG preoperatively and at 6 weeks, 3 and 6 months, and 1 and 2 years postoperatively. Patient-reported outcome measures (PROMs) were also evaluated. The mean 2MWT, TUG, and PROM results were compared between groups at each time point.

Results: The mean 2MWT distance after UKA was significantly longer than that after TKA at 6 weeks (96.5 ± 22.6 m for UKA compared with 81.1 ± 19.1 m for TKA; difference, 18 m [95% confidence interval (CI),10.4 to 25.6 m]; $p < 0.001$), 3 months (102.1± 24.4 compared with 87.5 ± 22.3 m; difference, 14.7 m [95% CI, 5.4 to 24.0 m]; $p = 0.002$), and 6 months (102.8 ± 16.2 compared with 89.6 ± 15.3 m; difference, 13.2 m [95% CI, 6.9 to 19.5 m]; $p < 0.001$). The values at 1 and 2 years were similar after UKA and TKA. The mean TUG after UKA was also significantly shorter than that after TKA at 6 weeks and 3 months. The mean PROMs were similar after both treatments, with the exception of the Oxford Knee Score and subscales of the Knee injury and Osteoarthritis Outcome Score at 6 weeks and 3 months postoperatively.

Conclusions: The 2MWT indicated that UKA for isolated medial knee OA enabled faster recovery than TKA did at 6 weeks to 6 months, and earlier recovery was also seen with the TUG at 6 weeks to 3 months. The 2MWT and TUG results after UKA and TKA were similar to one another at 1 and 2 years.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

Total knee arthroplasty (TKA) and unicompartmental knee arthroplasty (UKA) have both been recognized for their favorable clinical outcomes[1-4], but UKA exhibits lower survivorship than TKA in registry-based studies[5-8]. Nevertheless, UKA remains an option for medial knee osteoarthritis (OA) because it enables faster recovery[9,10] and greater range of motion (ROM)[8,10,11] compared with TKA. Functional recovery after UKA and TKA for knee OA is usually measured using patient-reported outcome measures (PROMs), questionnaires that provide data only on patient perception of their physical function. However, recent studies have indicated that actual functional recovery is overestimated by PROMs[12,13]. In contrast, performance-based tests, including the 2-minute walk test (2MWT) and Timed Up-and-Go test (TUG), directly assess a patient's physical function. The 2MWT is used to determine a patient's endurance or walking capacity[14], whereas the TUG is used to evaluate the patient's functional mobility, balance, and risk of falling[14-16]. Therefore, the 2MWT and TUG can capture the actual improvement in functional status and reveal a patient's ability to perform a specific task or action[17]. The 2MWT and TUG have also demonstrated validity, reliability, and responsiveness after TKA[18,19].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H263).

A **data-sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H265).

Prior studies have demonstrated that quadriceps muscle strength recovers to a normal level at 1 year of follow-up after TKA[20-24], resulting in abnormally low gait speed[25-27]. In contrast, quadriceps muscle strength showed a return to normal at an average of 6 months of follow-up after UKA[28]. TKA has a greater effect on knee biomechanics because of the extent of surgical dissection of the quadriceps, elimination of anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL) function, and replacement of 2 or 3 compartments, which may be the cause of the slower recovery of quadriceps muscle strength compared with that after UKA[29,30]. In contrast, UKA replaces only 1 compartment, limits the dissection of the quadriceps, and preserves the cruciate ligaments. Therefore, this randomized controlled trial aimed to compare the 2MWT and TUG results between UKA and TKA without patellar resurfacing for isolated medial knee OA. We hypothesized that UKA yields faster functional recovery than TKA as measured with the 2MWT and TUG.

Materials and Methods

Study Design and Patient Selection

A prospective, double-blinded, randomized controlled trial was conducted from September 2016 to April 2019 at Thammasat University Hospital, Pathum Thani, Thailand. The study was approved by the Human Research Ethics Committee of the Faculty of Medicine, Thammasat University (Reg. no.: MTU-EC-OT-2-172/61). The trial was registered at ClinicalTrials.gov (Reg. no.: NCT04419129).

The inclusion criteria were medial knee OA; patient age of 50 to 85 years; varus deformity of 0 to 10° based on the anatomic tibiofemoral angle (aTFA) (Fig. 1); ROM of ≥90°; flexion contracture of ≤15°; absence of definite joint-space narrowing of the lateral compartment and of the lateral patellofemoral joint, according to the Kellgren-Lawrence (KL) grading system[31], on a skyline view radiograph; and American Society of Anesthesiologists (ASA) classification of I or II[32]. The exclusion criteria were the need for surgery on the contralateral side; intraoperatively determined ACL insufficiency; intraoperatively determined full-thickness cartilage loss in the lateral compartment; severe bone loss; grooving of the lateral facet of the patella; a diagnosis of spontaneous osteonecrosis of the knee (SPONK); or the presence of inflammatory joint disease, gout, or posttraumatic arthritis. The indication for surgery was medial OA that was refractory to nonoperative treatment in a neutral knee or one with a passively correctable varus deformity. The contraindications to both TKA and UKA were an active knee infection, a remote source of infection, a nonfunctional extensor mechanism, and severe untreated peripheral arterial disease.

A total of 110 patients with isolated medial knee OA were randomized to receive UKA or TKA (55 patients each). Eleven patients were excluded from the final analysis (Fig. 2), leaving 50 patients who had undergone medial mobile-bearing UKA (Oxford Partial Knee; Zimmer Biomet) and 49 patients who had undergone posterior stabilized fixed-bearing TKA (Vanguard Complete Knee System; Zimmer Biomet), all performed by a single surgeon (B.P.).

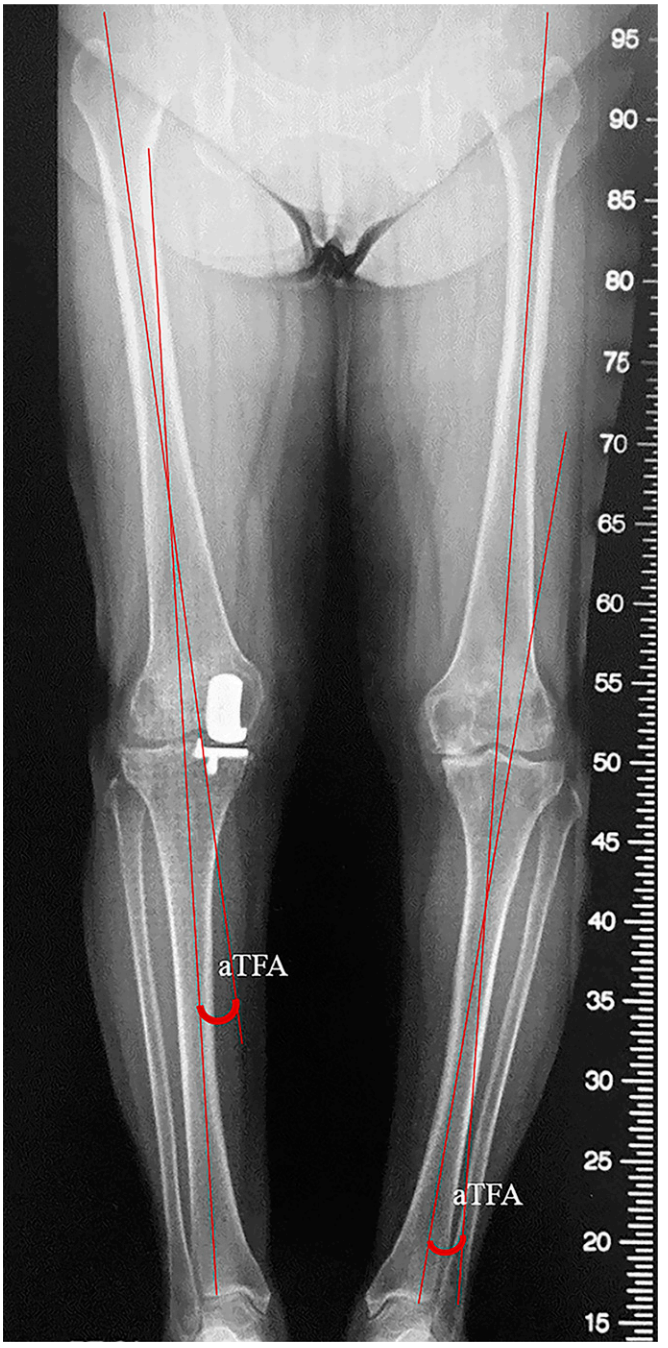

Fig. 1

Knee alignment was calculated based on the anatomic tibiofemoral angle (aTFA) on a full-length standing anteroposterior radiograph of the lower extremity.

Randomization and Blinding

Patients were assigned to receive UKA or TKA using a list of numbers generated by block randomization (www.randomizer.org). The randomization was performed using a block size of 2 at the preoperative outpatient visit by an external researcher who did not participate in the study. The outcome assessor and participants were blinded during the trial.

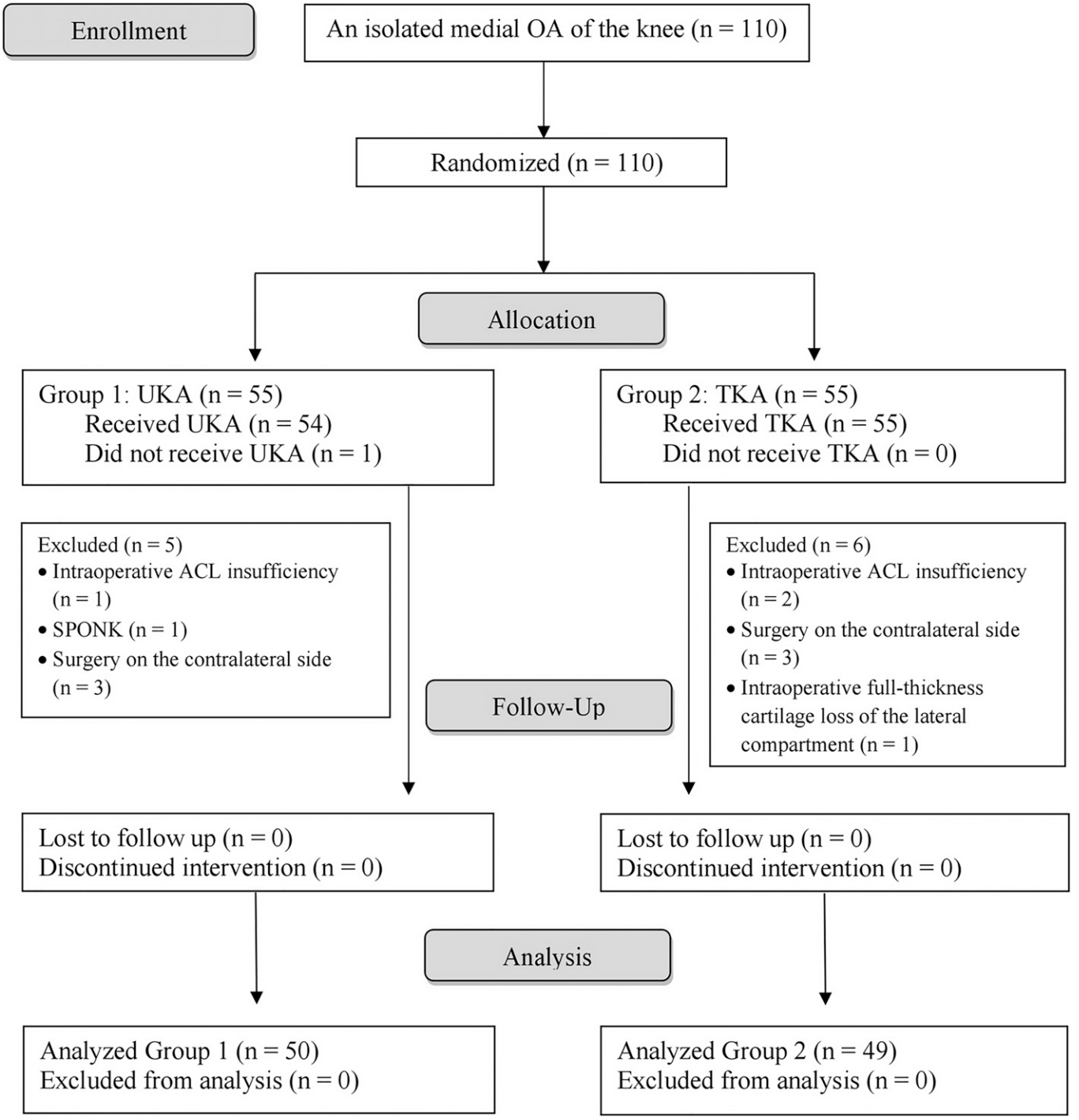

Fig. 2

Study flowchart. OA = osteoarthritis, UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty, ACL = anterior cruciate ligament, SPONK = spontaneous osteonecrosis of the knee.

Outcome Measures

The baseline patient characteristics, including age, sex, side, body mass index (BMI), varus deformity, flexion contracture, ROM, lateral compartment arthritis based on KL grading[31], patellofemoral arthritis based on KL grading[31], ASA classification[32], and quadriceps muscle strength using the Medical Research Council scale[33], were recorded (Table I). The results of the 2 performance-based tests, the 2MWT and TUG, were recorded by a research assistant in a blinded fashion. In the 2MWT, the patients were asked to walk as fast as possible. At the end of 2 minutes, the distance in meters from the starting point was recorded. The patients then rested for approximately 30 minutes and were

TABLE I Baseline Patient Characteristics*

Variable	UKA (N = 50)	TKA (N = 49)	P Value†
Age‡ *(yr)*	66.3 ± 6.3 (52.1 to 81.2)	67.5 ± 8.1 (51.2 to 83.1)	0.39
Sex, male/female	13/37	15/34	0.32
Site, left/right	29/21	31/18	0.51
BMI‡ *(kg/m²)*	27.8 ± 4.5 (20.6 to 32.2)	26.3 ± 4.3 (16.9 to 38.6)	0.09
Varus deformity, aTFA‡ *(deg)*	6.1 ± 3.0 (0 to 10)	5.6 ± 2.7 (0 to 10)	0.41
Flexion contracture‡ *(deg)*	2.5 ± 3.6 (0 to 15)	1.4 ± 3.4 (0 to15)	0.16
Lateral compartment arthritis, KL grading *(no. [%])*			
Grade 0	33 (66.0%)	31 (63.3%)	0.68
Grade 1	14 (28.0%)	16 (32.6%)	0.51
Grade 2	3 (6.0%)	2 (4.1%)	0.47
Patellofemoral arthritis at medial facet, KL grading *(no. [%])*			
Grade 0	25 (50.0%)	24 (49.0%)	0.81
Grade 1	20 (40.0%)	19 (38.8%)	0.61
Grade 2	4 (8.0%)	5 (10.2%)	0.72
Grade 3	1 (2.0%)	1 (2.0%)	0.91
Patellofemoral arthritis at lateral facet, KL grading *(no. [%])*			
Grade 0	27 (54.0%)	28 (57.1%)	0.76
Grade 1	23 (46.0%)	21 (42.9%)	0.68
ASA classification *(no. [%])*			
I	2 (4.0%)	3 (6.1%)	0.74
II	48 (96.0%)	46 (93.9%)	0.65
Quadriceps muscle strength, MRC grading *(no. [%])*			
Grade 5	45 (90.0%)	45 (91.8%)	0.73
Grade 4	5 (10.0%)	4 (8.2%)	0.69
Range of motion‡ *(deg)*	116.2 ± 16.6 (90 to 150)	117.6 ± 16.6 (90 to 140)	0.64

*BMI = body mass index, UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty, ASA = American Society of Anesthesiologists, KL = Kellgren-Lawrence, aTFA = anatomic tibiofemoral angle, MRC = Medical Research Council. †Continuous data were evaluated using the Student t test, and proportional data were analyzed using the chi-square test. P values of <0.05 were considered significant. ‡Values are given as the mean and standard deviation, with the range in parentheses.

encouraged to perform the TUG. In the TUG, the patients began by sitting on a standard chair; the research assistant then asked the patients to stand up, walk 3 m, and return to sitting on the chair. The time in seconds that the patient was not seated (standing up from the chair, walking, and sitting back down) was recorded. The Knee Society Score (KSS)[34], Oxford Knee Score (OKS)[35], Forgotten Joint Score (FJS)[36], Knee injury and Osteoarthritis Outcome Score (KOOS)[37], and Kujala score[38] were also recorded by the same research assistant. The patients returned for follow-up at 6 weeks, 3 and 6 months, and 1 and 2 years. At each follow-up, the 2MWT, TUG, KSS, OKS, KOOS, Kujala score, and FJS were assessed by the same research assistant in a blinded fashion. Anteroposterior standing, lateral standing, skyline view, and 3-foot (1-m) standing radiographs were made at 2 years, and the component alignment, tibial slope, and tibiofemoral angle were recorded (Fig. 3). The postoperative ROM was also recorded at 2 years. Complications, including mobile-bearing dislocation, component loosening, fracture, and infection, were also recorded.

Surgical Technique

A skin incision was made from the upper pole of the patella to the medial aspect of the tibial tubercle. A mini-midvastus approach was used in all cases to prevent patellar maltracking[39]. Minimally invasive instrumentation was used in both groups. Operative time and intraoperative blood loss were recorded.

For the mobile-bearing medial UKA, the tibia was first cut to create a tibial slope of 7°. The proximal aspect of the tibia was cut 1 to 2 mm below the deepest part of the medial tibial plateau. The posterior condyle of the femur was cut to create a flexion gap, and then the distal aspect of the femur was cut to create equal flexion and extension gaps. The patella was tilted, and osteophytes were removed.

For the TKA, the distal aspect of the femur was cut with 5° of valgus relative to its anatomical axis. The femoral component was positioned in 3° of external rotation. The proximal aspect of the tibia was cut 2 mm below the deepest part of the medial tibial plateau, creating a tibial slope of 3°. Complete

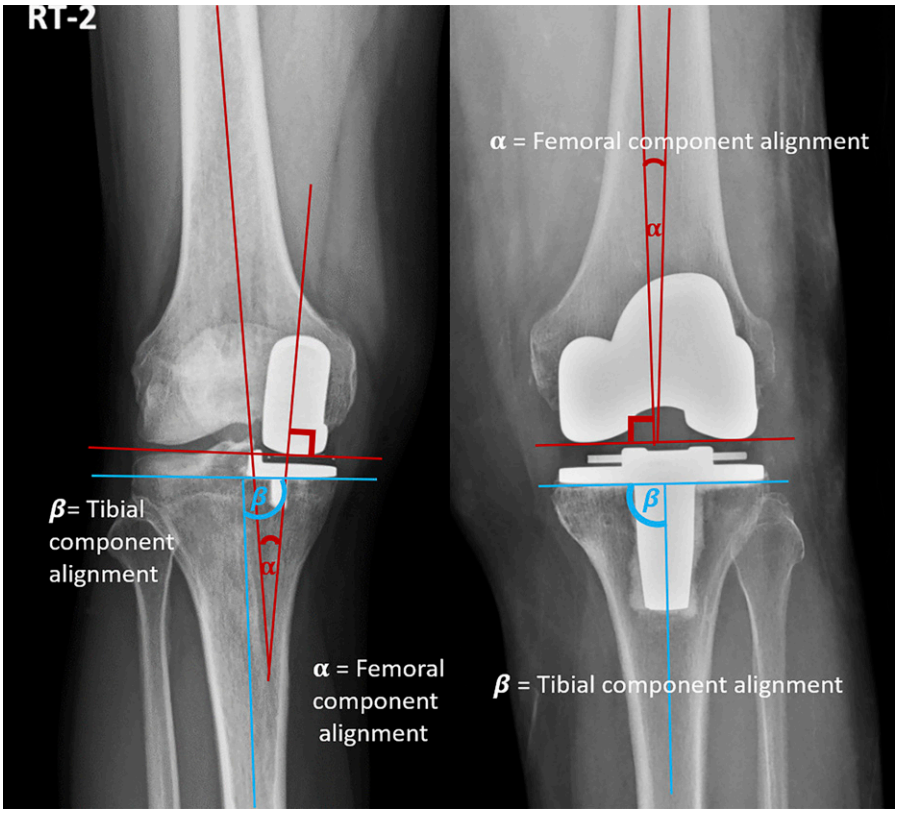

Fig. 3

The α angle is the femoral component alignment (angle between the anatomical axis of the femur and the axis of the femoral component). The β angle is the tibial component alignment (angle between the anatomical axis of the tibia and the axis of the tibial component). A β angle of <90° indicates varus alignment (degrees of varus = 90° – β), and a β angle of >90° indicates valgus alignment (degrees of valgus = β – 90°). The α and β angles were measured on a standing anteroposterior radiograph of the knee.

TABLE II Comparison of 2MWT and TUG Performance-Based Tests Between UKA and TKA*

Test and Time	UKA (N = 50)†	TKA (N = 49)†	P Value	Mean Difference Between Groups (95% CI)
2MWT *(m)*				
Preoperative	58.0 ± 31.8 (0 to 109.0)	69.3 ± 41.2 (0 to 142.0)	0.132	7.0 (−4.1 to 18.2)
6 weeks	96.5 ± 22.6 (56.7 to 146.7)	81.1 ± 19.1 (38.5 to 120.0)	<0.001	18.0 (10.4 to 25.6)
3 months	102.1 ± 24.4 (35.4 to 142.2)	87.5 ± 22.3 (35.4 to 127.6)	0.002	14.7 (5.4 to 24.0)
6 months	102.8 ± 16.2 (65.9 to 146.7)	89.6 ± 15.3 (38.5 to 120.0)	<0.001	13.2 (6.9 to 19.5)
1 year	110.5 ± 18.6 (70.5 to 137.0)	104.9 ± 16.3 (61.0 to 133.5)	0.113	5.6 (−1.3 to 12.6)
2 years	109.6 ± 14.9 (68.6 to 137.0)	104.9 ± 14.6 (61.0 to 133.5)	0.114	4.7 (−1.2 to 10.6)
TUG *(s)*				
Preoperative	16.5 ± 9.9 (0 to 43.7)	15.5 ± 10.7 (0 to 43.0)	0.302	−3.2 (−7.7 to 1.4)
6 weeks	11.9 ± 3.2 (5.7 to 18.5)	13.9 ± 3.0 (8.3 to 20.9)	<0.001	−2.2 (−3.3 to −1.0)
3 months	10.8 ± 3.3 (5.5 to 23.5)	13.3 ± 3.7 (7.6 to 23.5)	0.001	−2.5 (−3.9 to −1.1)
6 months	10.8 ± 2.2 (5.7 to 18.8)	11.6 ± 2.0 (8.8 to 20.8)	0.071	−0.8 (−1.6 to 0.1)
1 year	10.2 ± 2.7 (6.8 to 20.3)	11.0 ± 2.5 (7.4 to 15.2)	0.114	−0.4 (−1.8 to 0.9)
2 years	10.9 ± 4.4 (6.8 to 34.0)	11.2 ± 2.2 (7.4 to 17.8)	0.703	−0.3 (−1.7 to 1.1)

*2MWT = 2-minute walk test, TUG = Timed Up-and-Go test, UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty, CI = confidence interval. †Values are given as the mean and standard deviation, with the 95% CI in parentheses.

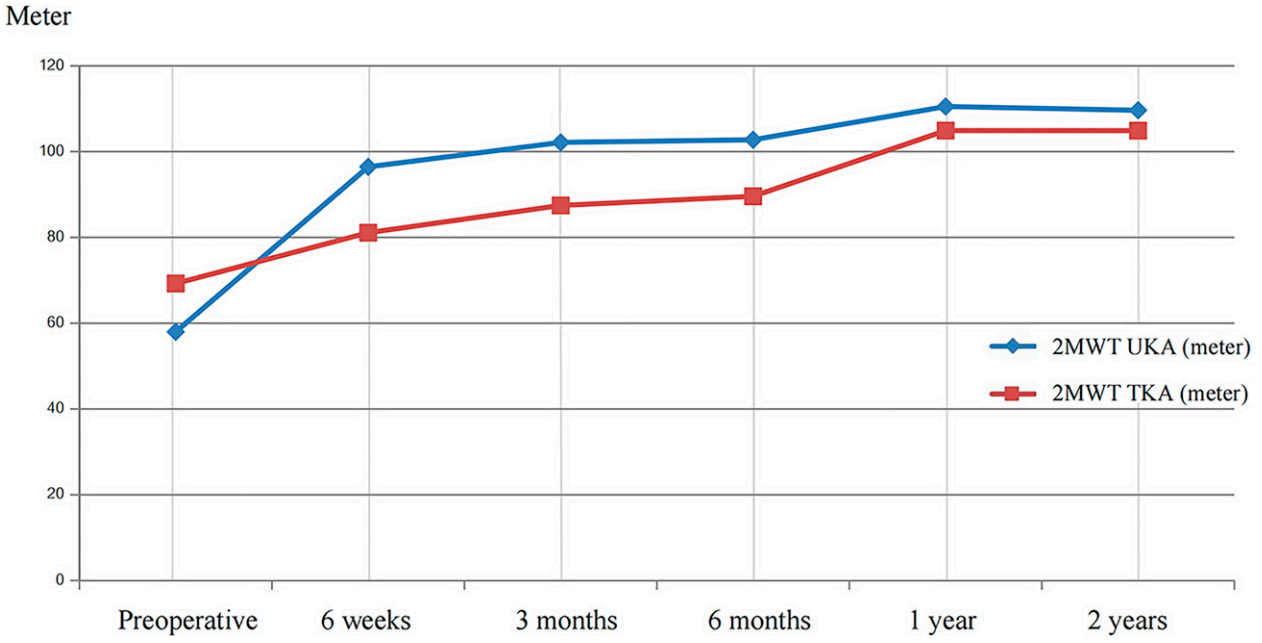

Fig. 4-A

Mean 2MWT at 6 weeks, 3 months, 6 months, 1 year, and 2 years after UKA versus TKA.

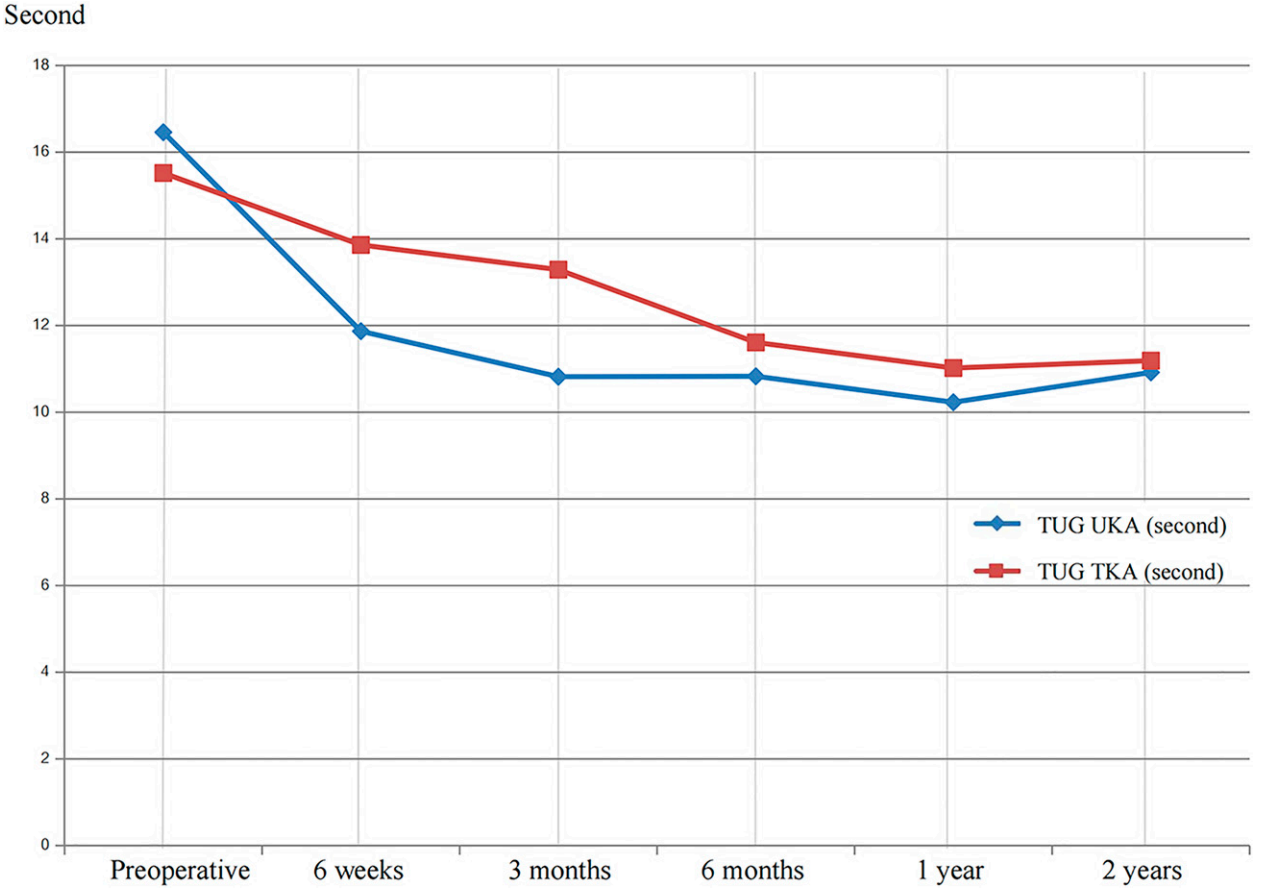

Fig. 4-B

Mean TUG at 6 weeks, 3 months, 6 months, 1 year, and 2 years after UKA versus TKA.

cutting of the femur and tibia was performed after the flexion and extension gaps were balanced. The patella was tilted, and osteophytes were removed.

The postoperative protocol was the same in both groups. Patients began ambulation as soon as possible. Active-assisted knee ROM exercises and quadriceps exercises were taught. Patients were discharged from the hospital once they no longer needed intravenous medicine to control acute postoperative pain, they could walk well with an ambulatory device, and there was no bleeding at the surgical site.

Statistical Analysis

The sample size was calculated on the basis of a pilot study involving a 6-week follow-up. The mean 2MWT distance (and standard deviation) at 6 weeks after UKA was 96 ± 21 m, and the mean 2MWT after TKA was 83 ± 23 m. The mean difference in the 2MWT between UKA and TKA was 12 m, and the number of patients needed to detect such a difference with a power of 90% and a 2-sided alpha of 5% was calculated to be 46 per arm.

Differences in the 2MWT, TUG, KSS, OKS, KOOS, FJS, and Kujala score between groups at all time points were assessed using the Student t test. Differences in age, BMI, ROM, aTFA, operative time, component alignment, posterior slope, and flexion contracture between groups were also assessed using the Student t test, and differences in categorical data were assessed using the chi-square test. All data were analyzed using IBM SPSS Statistics for Windows, version 24.

Source of Funding

No funding was received for this study.

Results

The preoperative baseline patient characteristics were not significantly different between the 2 groups (Tables I and II; see also Appendix Table S1). None of the patients were lost to follow-up.

Performance-Based Tests

The mean 2MWT distance after UKA was significantly longer than that after TKA at 6 weeks and 3 and 6 months, but not significantly different at 1 and 2 years (Table II). The mean TUG after UKA was significantly shorter than that after TKA at 6 weeks and 3 months; however, it was not significantly different at 6 months and 1 and 2 years (Table II).

The mean 2MWT and TUG at all time points after UKA were significantly better than their preoperative mean values (Figs. 4-A and 4-B; see also Appendix Table S2). The mean 2MWT and TUG after TKA were also significantly better than their preoperative means at all time points, with the exception of the mean TUG at 6 weeks (Fig. 4-B; see also Appendix Table S2).

PROMs

The mean PROMs were similar between the 2 treatments, with the exception of the OKS and subscales of the KOOS at 6 weeks and 3 months postoperatively (Figs. 5-A and 5-B; see also Appendix Table S1). The mean PROMs after both procedures

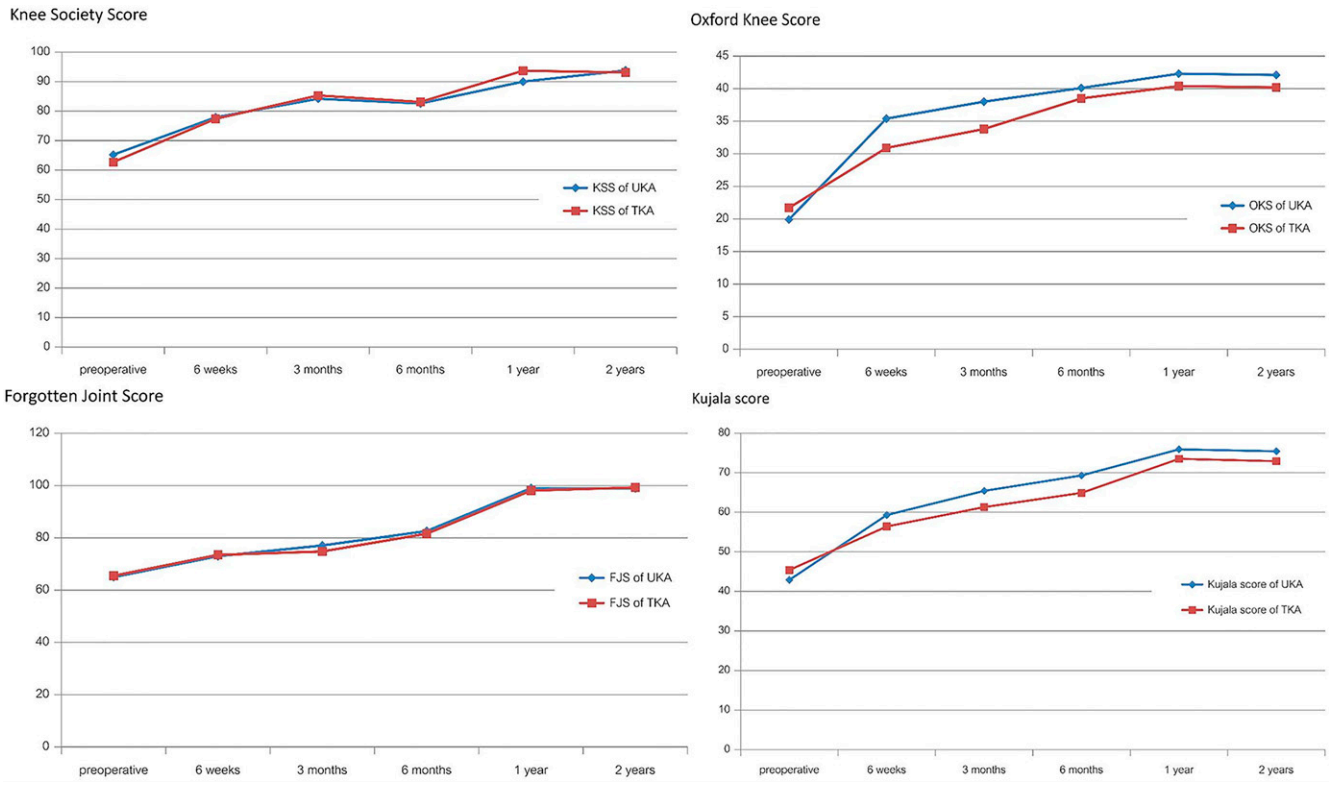

Fig. 5-A

Mean KSS, OKS, FJS, and Kujala score at 6 weeks, 3 months, 6 months, 1 year, and 2 years after UKA versus TKA.

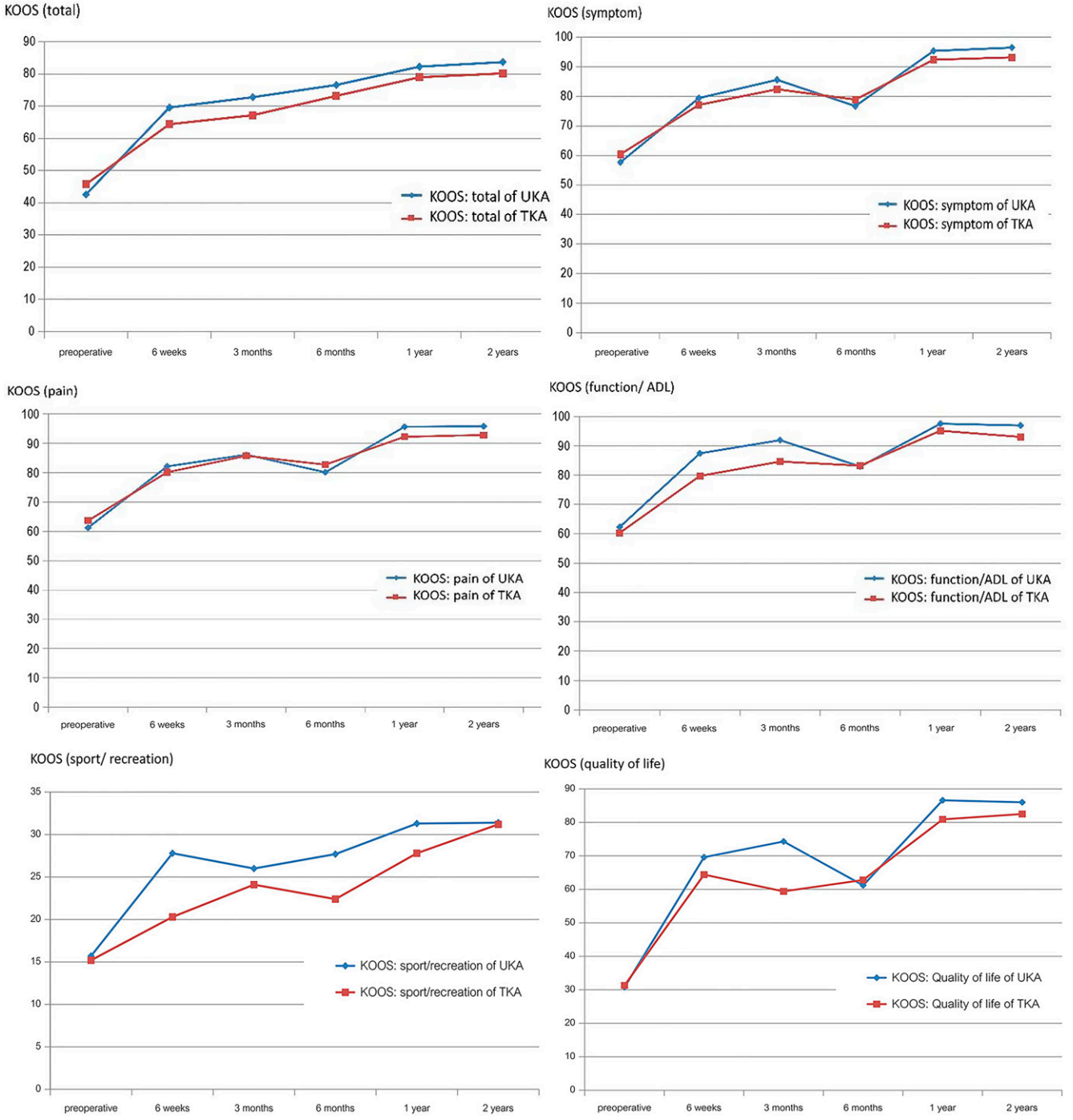

Fig. 5-B

Mean KOOS at 6 weeks, 3 months, 6 months, 1 year, and 2 years after UKA versus TKA. ADL = activities of daily living.

were significantly better than their preoperative mean values at all time points (Figs. 5-A and 5-B; see also Appendix Table S3).

Radiographic and Clinical Outcomes

The mean postoperative knee alignment, femoral component alignment, tibial component alignment, and posterior slope were similar between the 2 treatments (Table III). The operative time and intraoperative blood loss for UKA were significantly less than those for TKA. However, postoperative ROM demonstrated no difference between treatments (Table IV).

Complications

None of the patients developed complications (e.g., mobile-bearing dislocation, infection, or fracture) in either group.

TABLE III Comparison of Radiographic Outcomes Between UKA and TKA*

Variable	UKA (N = 50)†	TKA (N = 49)†	P Value	Mean Difference Between Groups (95% CI)
Postoperative knee alignment (aTFA) *(deg)*	5.1 ± 2.0 valgus (1 valgus to 10 valgus)	5.2 ± 1.5 valgus (2 valgus to 9 valgus)	0.481	0.02 (−0.71 to 0.74)
Femoral component alignment *(deg)*	5.4 ± 1.8 valgus (2 valgus to 10 valgus)	6.0 ± 1.8 valgus (2 valgus to 10 valgus)	0.104	−0.3 (−1 to 0.4)
Tibial component alignment *(deg)*	0.7 ± 1.0 varus (3 varus to 2 valgus)	0.9 ± 1.1 varus (1 varus to 3 valgus)	0.183	0.1 (−0.1 to 0.2)
Posterior slope *(deg)*	3.1 ± 1.8 (4 to 10)	2.6 ± 2.4 (5 to 10)	0.492	−0.3 (−1 to 0.3)

*UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty, CI = confidence interval, aTFA = anatomic tibiofemoral angle. †Values are given as the mean and standard deviation, with the 95% CI in parentheses.

Moreover, none of the patients required manipulation under anesthesia, reoperation, or revision TKA in either group.

Discussion

This randomized controlled trial demonstrated significantly faster recovery after UKA than after TKA, as measured with the 2MWT and TUG. The mean 2MWT was significantly better after UKA in the first 6 months, and the mean TUG was better in the first 3 months. The mean 2MWT and TUG were similar between the 2 groups at 1 and 2 years. The mean PROMs did not differ between UKA and TKA, except for the OKS and subscales of the KOOS at 6 weeks and 3 months postoperatively. To our knowledge, this is the first randomized controlled trial to demonstrate faster recovery of 2MWT and TUG performance after UKA than after TKA. The faster recovery of quadriceps muscle strength and improved gait[20-28], less soft-tissue trauma[29,30], preservation of ACL and PCL function, and replacement of only a single compartment in UKA are possible explanations for the faster recovery of 2MWT and TUG performance compared with TKA. The TUG difference between treatments was only observed in the first 3 months, but the difference in the 2MWT could be observed up to 6 months postoperatively. The 2MWT may require better recovery of physical fitness than the TUG, in which patients need to walk for only 10 to 16 seconds.

Nonetheless, the mean 2MWT distance was significantly longer than the preoperative mean values at all time points after both UKA and TKA. However, our study found that return of the 2MWT to its normal range (175 to 200 m at 60 to 89 years of age[40]) was not achievable even after 2 years of follow-up. The mean 2MWT distance at all time points after both UKA and TKA was less than the low end of the normal range for the aging population (175 m) by more than the minimum clinically important difference of 12.7 m[18,40]. Knee OA is a chronic disease that may cause a permanent loss in physical performance, preventing a return to the normal range[41-43]. Furthermore, claudication from the lumbar degenerative disease that often coexists with knee OA in older patients[44,45] may be another reason that 2MWT performance did not return to the normal range. Unnanuntana et al.[18] and Yuksel et al.[19] obtained results similar to those in our study; the 2MWT did not return to normal after TKA. The mean 2MWT was only 70 m (40% of normal) at 1 year after TKA according to the study by Unnanuntana et al.[18] and 120 m (69%) at a minimum follow-up of 6 months according to Yuksel et al.[19].

The mean TUG values returned to the normal range at 6 weeks after UKA and 6 months after TKA in the present study. The normal range for the TUG in a healthy 65 to 86-year-old is 8.5 to 13 seconds[15,46]. Previous studies have demonstrated that a TUG of >13 seconds is associated with balance impairment and higher

TABLE IV Comparison of Clinical Outcomes Between UKA and TKA*

Variable	UKA (N = 50)†	TKA (N = 49)†	P Value	Mean Difference Between Groups (95% CI)
Operative time *(min)*	75.6 ± 14.7 (48 to 117)	93.7 ± 13.9 (55 to 116)	<0.001	18.0 (12.5 to 23.5)
Intraoperative blood loss *(mL)*	16.8 ± 16.1 (5 to 50)	34.8 ± 36.6 (5 to 200)	0.014	19.3 (10.4 to 28.2)
Range of motion *(deg)*	125.2 ± 11.6 (90 to 145)	122.8 ± 15.8 (90 to 150)	0.382	2.4 (−3.1 to 8)
Hospital stay *(day)*	2.1 ± 0.4 (1 to 4)	2.3 ± 0.6 (1 to 4)	0.064	−0.2 (−0.4 to 0.1)

*UKA = unicompartmental knee arthroplasty, TKA = total knee arthroplasty, CI = confidence interval. †Values are given as the mean and standard deviation, with the 95% CI in parentheses.

risks of falling[15,46]. Yuksel et al.[19] found that the TUG returned to normal (<13 seconds) at a minimum of 6 months of follow-up. Nevertheless, that study lacked a specific follow-up time point and included patients with various grades of knee OA. The study by Unnanuntana et al.[18] found that the TUG in patients with tricompartmental knee OA did not return to normal (<13 seconds) at the 1-year follow-up after TKA. In comparison, we found that the mean TUG of patients with medial knee OA returned to normal at 6 weeks after UKA and 6 months after TKA.

The present study demonstrates that PROMs are not entirely capable of detecting the difference in functional recovery between UKA and TKA. The mean OKS and subscales of the KOOS at 6 months after UKA were similar to those after TKA, but the 2MWT distance at 6 months after TKA was still significantly shorter than that after UKA. However, PROMs are still important because they can assess some activities of daily living, such as stepping up and down and putting on socks and pants, that are not assessed in performance-based tests. Therefore, routine use of the 2MWT and TUG combined with PROMs in standard clinical assessments is recommended to capture the actual improvement in physical status and provide a more comprehensive perspective of functional recovery after UKA and TKA.

This study had several limitations. First, we did not assess OA in the contralateral knee and lumbar spine[44,45], which might have had a major influence on the 2MWT and TUG results. Second, all UKAs and TKAs were performed by a single surgeon. Therefore, the surgeon could not be blinded to the treatment, which might have caused bias. Third, the patients in our study underwent mobile-bearing UKA. Previous studies have shown the kinematics after mobile-bearing UKA to be better than those after fixed-bearing UKA[47-49], and normal patellofemoral forces were well preserved[47,50]. Therefore, comparison of the results of fixed-bearing and mobile-bearing UKA is a potential opportunity for future research. Fourth, a small number of patients were excluded after randomization. However, they only constituted approximately 10% of the study population, and the UKA and TKA groups that were analyzed demonstrated similar baseline characteristics. Finally, our study did not take comorbidities into account, thus potentially affecting the 2MWT and TUG results in both groups. However, the effect might have been minor because both groups had a similar ASA classification.

In conclusion, UKA enabled better recovery of 2MWT performance than TKA from 6 weeks to 6 months and of TUG performance from 6 weeks to 3 months in patients with isolated medial knee OA. By 1 year and 2 years, the 2MWT and TUG were similar between treatments.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H264). ■

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Current Concepts Review

The Role of Dual-Mobility Components in Total Hip Arthroplasty

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- Dual mobility (DM) refers to a now widely available option for total hip articulation. DM implants feature a small inner head, a hard bearing, that connects via a taper fit onto the femoral trunnion. This head freely rotates but is encased inside a larger, outer polyethylene head that articulates with a smooth acetabular component.
- DM acetabular components are available in the form of a monoblock shell or as a liner that is impacted into a modular shell, providing a metal articulation for the polyethylene outer head.
- DM is designed to increase hip stability by providing the arthroplasty construct with a higher jump distance, head-to-neck ratio, and range of motion prior to impingement.
- The use of DM in total hip arthroplasty continues to increase in the United States for both primary and revision arthroplasty. Surgeons should be aware of the potential benefits and pitfalls.
- Long-term data are lacking, especially for modular DM implants. Points of concern include a potential for accelerated polyethylene wear, intraprosthetic dislocation, and modular backside fretting corrosion.

Dual-mobility (DM) components have enjoyed an explosion in popularity due to their dual articulation and resultant ability to minimize the difference between the outside acetabular component (hereafter referred to as "shell") diameter and the articulating femoral head diameter.

The purpose of the present review is to describe the basic biomechanical concepts governing DM implants, the current options available from manufacturers in North America, outcomes associated with the available implants, and potential problems with the technology.

A Brief History of DM Implants

DM implants originated in France in the 1970s, developed by Professor Gilles Bousquet and André Rambert, in an attempt to maximize range of motion without dislocation (Figs. 1-A, 1-B, and 1-C)[1,2]. Instability and polyethylene wear remain leading causes of total hip arthroplasty (THA) failure. Instability accounts for 18.3% of revision THA procedures in the U.S., with osteolysis and wear accounting for another 4.9%; aseptic loosening and "mechanical complications" account for another 15.9% and 14.9%, respectively[3].

While DM implants became a common, accepted choice in France, widespread international adoption was much slower[4]. DM implants have only been approved for use in the U.S. for a little over a decade, with U.S. Food and Drug Administration (FDA) clearance of the Stryker Monoblock Anatomic DM (Stryker) in 2009 and clearance of the Stryker Modular DM in 2011[5]. Since that time, other implant manufacturers have developed their own DM options. Table I lists some of the commonly available DM cups in the U.S.

How Do DM Articulations Prevent Dislocation?

The benefit of DM is the large external articulation[6]. By maximizing head size, DM constructs maximize both the jump distance necessary for dislocation as well as the head-to-neck ratio, increasing range of motion prior to impingement[7].

An additional proposed advantage of DM components is the double articulation, with the metallic or ceramic inner femoral

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H349).

Fig. 1-A

Fig. 1-B

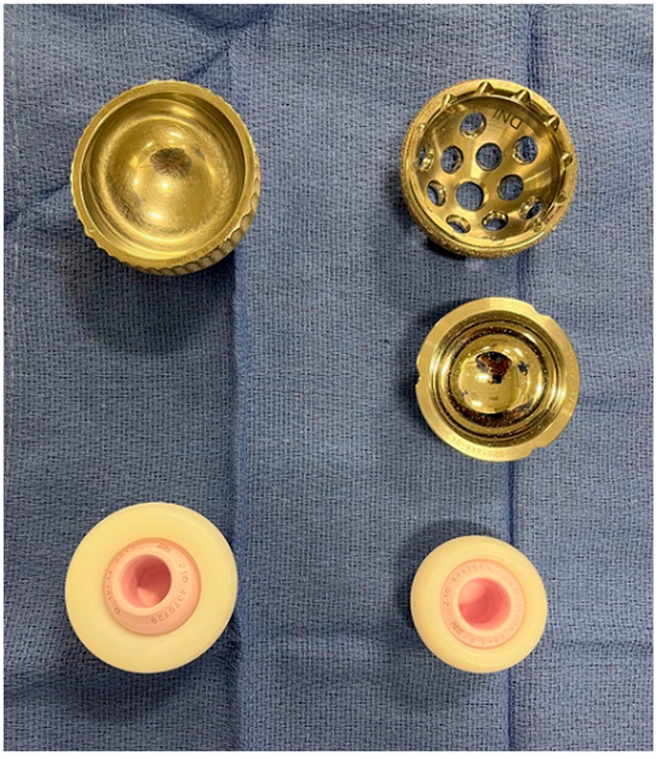

Fig. 1-C

Figs. 1-A, 1-B, and 1-C Photographs showing the monoblock and modular DM components (DePuy Synthes). **Fig. 1-A** Monoblock DM component. **Fig. 1-B** Modular DM component. **Fig. 1-C** Comparison of the monoblock and modular DM components. Note how the polyethylene head diameter decreases with the modular component relative to the outer shell diameter.

TABLE I Current Dual-Mobility Implant Options That Are FDA-Approved for Use in the United States*

Company	Cup	Monoblock or Modular	Material	Size Options *(mm)*	Thinnest Polyethylene *(mm)*	Shell/ Outer Head Difference *(mm)*	Shell Size for 28-mm Head *(mm)*	Charnley Bore (Cylindrosphere)	Modular Interface
DePuy Synthes	BI-MENTUM	Monoblock	Stainless steel cup, plasma sprayed titanium with hydroxyapatite coating	41-69	6.4	6	47	0 mm	NA
	Pinnacle DM	Modular	CoCr modular liner, all-titanium cup	48-72	6.4	13	54	3 mm	Circumferential Morse taper with a rounded back, no central peg
Stryker	ADM	Monoblock	CoCr cup with plasma sprayed titanium overlayed with hydroxyapatite	46-64	5.9	6	46	0 mm	NA
	MDM	Modular	CoCr modular liner, all-titanium cup	46-80	6.7	Increases from 10	52	2.2 mm	Peripheral shell flange scallops that accept the liner tabs, central peg
Zimmer Biomet	M2a-Magnum	Monoblock	CoCr cup with plasma sprayed titanium	44-66	4.8	6	44	Negative (16° coverage)	NA
	G7 DM	Modular	CoCr modular liner, all-titanium cup	42-80	4.6	Increases from 10	48	0 mm	Central apical plug
Medacta	Mpact DM	Monoblock	Stainless steel cup with plasma sprayed titanium	42-66	5	8	48	5° lip	NA
	Mpact DM Converter	Modular	CoCr modular liner, titanium cup	50-76	6	Increases from 14	56	5° lip	18° taper + micro threads
DJO	EMPOWR	Modular	CoCr modular liner, titanium cup with P^2 coating	48-70	4.7	10	48	1.5 mm	Dome with peripheral pegs as well as center peg that locks into apical plug
Smith & Nephew	POLARCUP	Monoblock	CoCr cup with plasma-sprayed titanium	47-69	6.5	6	47	6° lip	NA
	OR3O	Modular	Oxidized zirconium cup	48-70	5.5	Increases from 12	54	0 mm	Locking taper with central peg

*FDA = U.S. Food and Drug Administration, ADM = anatomic dual-mobility, MDM = modular dual-mobility, NA = not available, Co = cobalt, Cr = chromium.

head articulating with the larger polyethylene head[8] (Figs. 2 and 3). A standard 22 or 28-mm spherical cobalt or ceramic head has an initially unrestricted motion against the soft polyethylene concave surface. At the extremes of range of motion for this inner bearing, impingement of the trunnion against the outer head drives the second, external bearing to articulate against the metal shell or metal liner. This range of motion is subsequently only limited when impingement occurs between the femoral trunnion and the acetabular component. At this point, further motion in the same direction will cause levering of the head away from the center of rotation of the shell until dislocation. A retrieval study of 33 modular DM constructs showed wear on both the outer and inner surfaces of the polyethylene head, although more wear was seen at the inner surface[9]. This finding suggests that the motion of the femoral head against the inner polyethylene bearing dominates. However, what is commonly misunderstood is that this increased arc of motion prior to impingement is no different with a DM double articulation than with a solid head of the same outer diameter (Fig. 2).

Monoblock Versus Modular

The outer polyethylene of a DM femoral head must articulate against a smooth, metallic acetabular surface. This smooth surface can be in the form of a monoblock shell, a purpose-built

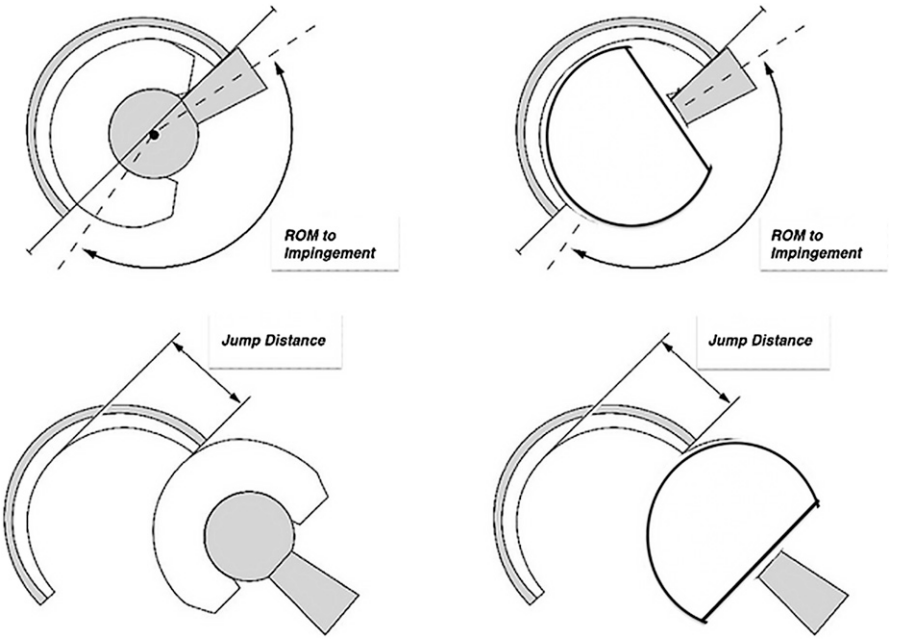

Fig. 2

A double articulation does not necessarily increase the jump distance or range of motion (ROM) to impingement relative to a monoblock femoral head of equivalent size. (Reprinted from: J Arthroplasty, 36[8], Lygrisse KA, Matzko C, Shah RP, Macaulay W, Cooper JH, Schwarzkopf R, Hepinstall MS. Femoral Neck Notching in Dual Mobility Implants: Is This a Reason for Concern? 2843-9, Copyright 2021, with permission from Elsevier.)

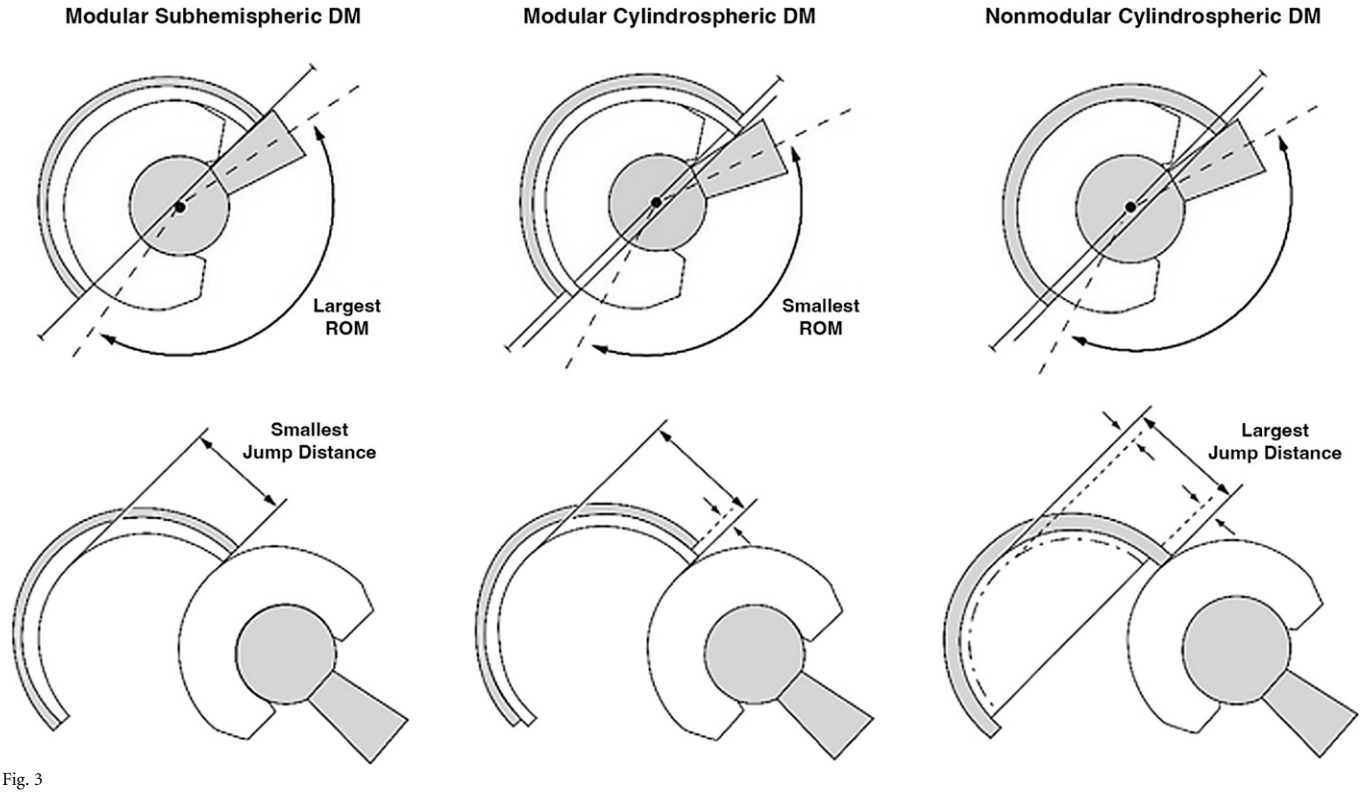

Fig. 3

Illustrations depicting modular subhemispheric, modular cylindrospheric, and nonmodular cylindrospheric implants and the influence of design on range of motion (ROM) and jump distance. Reprinted from: J Arthroplasty, 36[8], Lygrisse KA, Matzko C, Shah RP, Macaulay W, Cooper JH, Schwarzkopf R, Hepinstall MS. Femoral Neck Notching in Dual Mobility Implants: Is This a Reason for Concern?, 2843-9, Copyright 2021, with permission from Elsevier.)

implant that will only accept a DM articulation, or a modular shell—the same shell used with polyethylene fixed liners that is converted to DM by coupling to a smooth metallic liner. Although monoblock and modular DM shells are different implants, with potentially different long-term outcomes, the literature often combines the two. The 2021 American Joint Replacement Registry (AJRR) Annual Report, which showed a worse rate of revision for DM compared with traditional articulations, did not distinguish between monoblock and modular shells[3].

Several monoblock and modular DM options are now available (Table I). Monoblock options benefit from the largest head-to-shell ratio and avoid the modular metal liner, and this is the design that was granted initial FDA approval. In a study of Stryker ADM (anatomic DM) monoblock DM cups, this monoblock DM construct had larger average head sizes than traditional fixed-bearing prostheses (11.5 mm for ≤50-mm cups and 16.3 mm for ≥58-mm cups)[10].

The drawbacks of selecting a monoblock versus a modular shell are twofold. First, the outer articulation of a DM design requires that the monoblock shell have a smooth, polished inner finish. This limits the use of conventional screw holes that could lead to a sharp edge grating against the soft outer head. Some monoblock designs have options for flush pegs and for peripheral tab screws.

Unlike monoblock shells, modular shells can accept acetabular screw fixation and other liner options. However, the modular liner leads to a smaller allowable head diameter for a given shell size compared with the monoblock option (Fig. 1-C). Furthermore, complications (e.g., corrosion, stem notching, and malseating) have been linked to the shell-liner interface.

The Stryker Modular DM was approved using the monoblock component as the predicate device. The duration of follow-up on this implant is now just over 10 years; thus, long-term outcome data are lacking. Since the approval of this implant in 2011, many manufacturers have released their own modular DM options (Table I).

Shell-to-Head Diameter Differences

The larger the outer head, the larger the jump distance and range of motion prior to stem impingement (Figs. 2 and 3). For the purposes of stability, the closer the head size is to the shell size, the more stable the implant. This effect strongly favors monoblock over modular DM options (Table I).

The Charnley Bore

The Charnley bore (also called a cylindrosphere) is a cylindrical lip extending beyond the plane of the hemispherical acetabular articulation (Fig. 3). This type of lipped liner extends the articular surface beyond the hemisphere and offers an increase in the jump distance. However, it allows a decreased arc of motion. Of course, this is true of any conventional polyethylene articulation. With smaller head sizes, the effect of a cylindrical lip on the arc of motion leads to early impingement between the trunnion and liner. With the large head size of DM implants, the cylindrosphere will increase the jump distance with a smaller effect on the arc of motion.

Some monoblock and modular DM options have a symmetrical lip around the entire rim of the articulating surface. Others only have this lip on 1 side of the hemisphere, a gradual build-out that provides additional cover asymmetrically and is designed to be implanted toward the site of greatest instability (Table I).

Smallest Shell Size Accepting a 28-mm Inner Head

Most DM systems mandate a switch from 28 to 22-mm inner heads as the shell size decreases. A 22-mm inner head avoids a thin polyethylene outer head in the smallest shells, which could lead to catastrophic failure or accelerated terminal wear.

There are several potential benefits to utilizing a 28-mm head with smaller shell sizes, polyethylene thickness notwithstanding. A 28-mm head allows the surgeon a greater choice of head options than are available with a 22-mm head. A larger inner head is also expected to have a higher inner-articulation range of motion prior to femoral neck impingement on the outer-head polyethylene, potentially delaying the wear around the snap-fit locking mechanism. A 28-mm head has been shown to be protective against intraprosthetic dislocations when compared with a 22-mm head[11].

Thinnest Nominal Polyethylene

The cross-sectional width of the polyethylene is as thin as the difference between the diameter of the outer head and the diameter of the inner head. For each system, the smallest outer head that accepts a 28-mm inner head dictates the thinnest polyethylene. The polyethylene of a DM outer head is thinnest at its apex. The thinnest nominal polyethylene depends on the system and on the shell size and inner head combination employed (Table I). Although present-day highly cross-linked polyethylene (HXLPE) has better wear characteristics than historical controls, long-term data on the wear rates are not available[12]. Historically, the minimal thickness of traditional acetabular liners was greater than what is currently available in some DM outer heads[13].

The Modular Shell-to-Liner Interface

Modular DM necessitates the coupling of a metal liner into the metal shell. While acetabular shells are predominantly manufactured from titanium alloys, nearly all modular DM liners are manufactured from cobalt-chromium. Malseating concerns have led to different coupling and alignment strategies with the aim of minimizing the malseating and backside corrosion (Table I).

Published Outcomes

Published reports on the longevity of DM implants have lacked long-term outcomes. Currently, long-term outcome data for monoblock components are limited to the French experience, and no long-term data are available for modular DM components. Additionally, available data are confounded by the selective use of DM in high-risk arthroplasties, rather than

in elective primary, uncomplicated arthroplasties. Overall, at early to intermediate-term follow-up, DM appears to have excellent survivorship with low rates of dislocation and aseptic loosening[14]. Table II presents some of the available outcome data, including those from several systematic reviews, for DM articulations in primary THA, revision THA, and THA for femoral neck fracture[14,15,17,18,20-24,41,44].

Lawrie et al., in a prospective cohort study of 43 patients <65 years of age who received a modular dual-mobility implant, evaluated the results at 2 years and then again at 5 years[17,18]. In the group of 25 patients with complete 5-year follow-up, the authors reported a mild increase in cobalt and titanium levels at 1 year post-implantation without significant further change by 5 years.

Most studies comparing DM and conventional articulations do not control for the effective head size difference between the groups. Hartzler et al. performed a single-center retrospective review comparing revision THA with either a modular DM or conventional 40-mm head[20]. Despite using DM in the population at higher risk for future dislocation, they

TABLE II Summary of Published Outcomes of Dual-Mobility Implants*

Study	THAs	Study Details	Level of Evidence	Modular or Monoblock DM	Mean Follow-up *(yr)*	All-Cause Survivorship	Dislocation Rate	IPD Rate	Aseptic Loosening Rate
Primary THA									
Lawrie et al. 2021[17]	43	Prospective study of patients <65 years old	II	Modular	5	98%	0.00%	0.00%	2.00%
Nam et al. 2019[18]	43	Prospective study of patients <65 years old	II	Modular	2	100%	0.00%	0.00%	0.00%
Darrith et al. 2018[15]	10,783	Systematic review	IV	Mixed	8.5	98%	0.46%	1.10%	1.30%
De Martino et al. 2017[44]	12,844	Systematic review	IV	Mixed	6.8	NR	0.90%	0.70%	NR
Revision THA									
Hernandez et al. 2021[23]	94	Retrospective review	III	Modular	5.5	81%	11%	3.20%	4.00%
Sonn et al. 2021[21]	72	Retrospective review (DM vs. ≥40-mm heads)	III	Mixed	3.6	89.30%	6.90%	4.00%	NR
Hartzler et al. 2018[20]	126	Retrospective review (DM vs. 40-mm heads)	III	Modular	3.3	94%	3.00%	0.00%	1.60%
Sutter et al. 2017[22]	64	Retrospective review	III	Modular	3.2	91%	3.00%	0.00%	3.00%
Darrith et al. 2018[15]	3,008	Systematic review	IV	Mixed	5.4	96.60%	2.20%	0.30%	1.40%
Harwin et al. 2018[14]	85	Matched cohort comparison of DM to fixed-bearing	IV	Modular	4	95.30%	1.10%	0.00%	1.10%
Levin et al. 2018[19]	693	Systematic review	IV	Mixed	2.58	94.50%	2.20%	0.30%	0.70%
De Martino et al. 2017[44]	5,064	Systematic review	IV	Mixed	4.4	NR	3.00%	1.30%	NR
THA after femoral neck fracture									
You et al. 2020[24]	7,189	Systematic review of femoral neck fractures	IV	Mixed	2.6	95.60%	1.50%	0.04%	NR
Darrith et al. 2018[15]	554	Systematic review	IV	Mixed	1.3	97.80%	2.30%	0.18%	0.18%

*IPD = intraprosthetic dislocation, NR = not reported.

found a significantly improved survivorship free of dislocation (3% versus 10%) and an improved survivorship free of all-cause revision (6% versus 15%) in favor of the DM group. However, the average DM outer head size was 47 mm, compared with the 40-mm fixed heads. Sonn et al. retrospectively compared DM versus conventional articulations in a single-surgeon series of revision THAs[21]. In that study, DM implants with outer head sizes of ≥40 mm were compared with conventional head sizes of ≥40 mm. Interestingly, no difference in dislocation between these 2 groups of large-head articulations was seen (6.9% in the DM group, compared with 5.7% in the fixed group; p = 1.00).

Finally, there is some concern that the benefit of lower dislocation rates with DM may decrease over time. Investigators from a single center reported their early experience with modular DM for revision THA and reported only 2 dislocations following 64 revisions (prevalence, 3%) after a mean follow-up of 3.2 years, with no revisions required for the treatment of instability[22]. Another study from the same center evaluated an expanded series with longer follow-up of 5.5 years and demonstrated an overall rate of dislocation of 11%, with a reoperation rate for dislocation of 7%[23]. The authors noted a time-dependent, bimodal distribution to their observed dislocations, with 6 dislocations occurring in the short term (mean, 33 days after revision) and 4 in the intermediate term (mean, 4.3 years after revision).

Adoption in the United States

There is increasing adoption of DM in the U.S., with DM implants accounting for 10.2% of all elective primary THAs reported to the AJRR in 2020[3]. In addition, DM devices were implanted during 27.1% of revisions performed for instability in 2020, up from 17.7% in 2012[3].

DM is also experiencing high utilization in primary THA, particularly in female patients <50 years of age[25]. Higher usage is seen in association with diagnoses other than osteoarthritis, including osteonecrosis, dysplasia, femoral neck fracture, and posttraumatic arthritis[25]. The heightened interest in dislocation produced by the hip-spine relationship has led some to recommend DM for primary hip arthroplasty in patients with altered spinopelvic mechanics[26,27].

Potential DM Concerns

Polyethylene Wear

There is conflicting evidence on whether the second articulating surface may increase the polyethylene wear of DM implants. Early DM shell designs were associated with a high rate of aseptic loosening. Although this has been largely corrected in modern shell designs with improved ingrowth surfaces, the concern that the original failures were due to higher wear and osteolysis persisted[28].

This possibility of increased wear also was suggested in a radiographic study showing a larger bedding-in linear penetration of the DM polyethylene[29]. Although the linear-penetration rate of DM at 5 years approached historical controls, early penetration at 1 to 2 years was nearly twice that of conventional articulations, despite the fact that the DM implants were utilized in lower-activity patients. This finding may be a result of higher wear of the double articulation; specifically, the additional articulation between the convex surface of the larger polyethylene head and the concave metal liner of the acetabular cup increases the total surface area of articulating polyethylene in DM. However, the validity of radiographic analysis for wear calculations of DM implants remains controversial[30].

This higher wear rate has been disputed by other retrieval studies and in vitro experiments. Adam et al. examined 40 retrieved outer DM heads at an average of 8 years (range, 3 to 15.5 years) after implantation in monoblock DM constructs with traditional polyethylene and 22.2-mm inner heads[31]. Those authors found an average total linear wear of 0.082 ± 0.072 mm/year), which is similar to reported rates for traditional articulations of polyethylene against 22-mm metal heads[32]. This finding was confirmed in a separate explant wear study by Boyer et al., which showed equivalent volumetric wear between DM and traditional articulations[33].

Furthermore, in vitro biomechanical wear evaluation of modern HXLPE in DM heads has demonstrated excellent performance, even in simulations involving metal abrasions, impingement, and fibrosis of 1 of the 2 articulations[34,35]. In addition, it is likely that the newer polyethylene improves the longevity of the capture mechanism of the inner head, potentially leading to a lower rate of intraprosthetic dislocations. In fact, a retrieval analysis of HXLPE DM implants showed low rates of impingement notching against the outer head (21.5%; 20 of 93 retrieved DM heads)[36], a favorable rate when compared with conventional articulations (77%; 75 of 97 retrieved conventional polyethylene liners) (p < 0.001)[36,37].

Intraprosthetic Dislocation

Most dislocations in patients with a DM construct involve the outer polyethylene head dislocating from the acetabular shell. However, a unique failure mechanism of the DM implant occurs when the inner head dissociates from the outer head, known as intraprosthetic dislocation (IPD) (Fig. 4). Historically, this seems to have been a more common late-term consequence of polyethylene wear along the capture mechanism of the outer head[38-40]. Philippot et al. described their experience with IPD, organizing their perceived etiology into 3 types: (1) failure of the retentive rim, (2) fibrosis of the larger articulation leading to rim failure, and (3) IPD secondary to shell loosening[39]. IPDs also have been reported as a result of incomplete seating of the inner head within the outer head prior to implantation[41].

In the U.S., IPDs are frequently reported as an iatrogenic consequence of a failed closed reduction of a dislocated DM construct[16]. The outer head impinges on the rim of the shell or on the soft tissue, and a forceful reduction maneuver leads to a "bottle-opener effect," dissociating the inner head from the outer head. This dissociation allows the outer head to float freely within the pericapsular soft tissues. If an intraprosthetic dislocation is missed, the inner head will articulate directly with the acetabular metal liner[42] (Fig. 4). IPDs necessitate open reduction and revision[43].

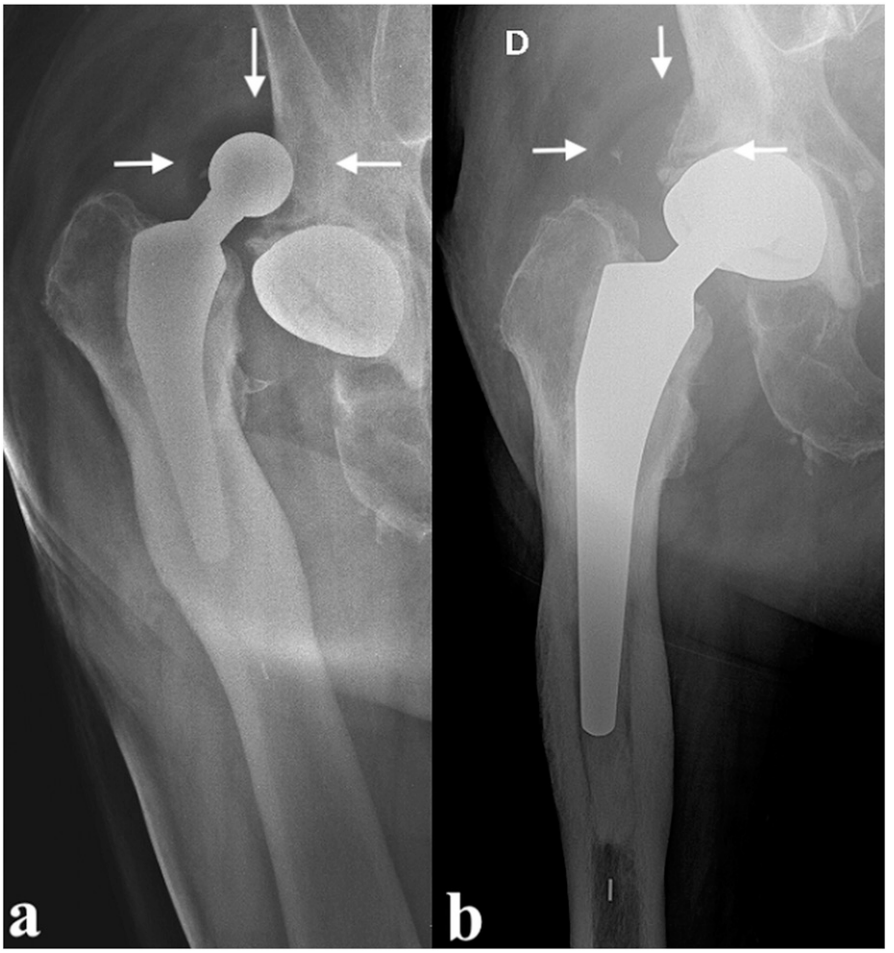

Fig. 4

Radiographs of the hip in a patient with a DM implant after closed reduction. Intraprosthetic dislocation is suspected on the basis of the eccentric placement of the femoral head in the acetabular shell and the "bubble sign" shadow of the expelled polyethylene outer head (arrows). (Reprinted from: Int J Surg Case Rep, 71, Rotini M, Cianforlini M, Aucone D, Pacetti E, Politano R. Iatrogenic intraprosthetic dislocation after closed reduction of dual mobility total hip arthroplasty: Report of two cases, 225-9, Copyright 2020, with permission of Elsevier.)

Systematic reviews of primary and revision THAs have shown low rates of IPD, ranging from 0.3% to 1.3%[19,44]. The rate of IPD may be decreasing with the use of HXLPE and 28-mm inner heads. Darrith et al. found no cases of IPD in studies of primary THAs performed after 2007 or those involving the use of 28-mm heads[15].

Some authors have recommended the use of general or spinal anesthetic during dislocated DM construct reductions in order to minimize the risk of intraprosthetic dislocation[23,43]. Close scrutiny of post-reduction radiographs is necessary to detect IPD, with computed tomography scanning being advised if radiographs are equivocal[43] (Fig. 4).

Malseating of the Liner

In modular DM implants, the smooth liner is impacted onto the already implanted shell. The shell has a tapered locking mechanism to retain the liner. If the modular liner is not perfectly aligned with the accepting shell, or if there is soft-tissue interposition, screw-head prominence, or accepting-shell deformity from the osseous press-fit, the locking mechanism may not perfectly accept the coupling. This leads to a canted seating of the liner into the shell, known as "malseating." This is a problem that precedes modular DM (MDM) implants and was seen in association with metal-backed alumina liners in ceramic-on-ceramic THA constructs[45].

Guntin et al., in a radiographic analysis of 239 primary and revision hip replacements that had been performed with modular DM constructs at a single institution from 2011 to 2020, found that 8 (6.8%) of 118 Stryker MDM liners and 4 (3.3%) of 121 Zimmer G7 DM liners were incongruous with the acetabular shell[46]. A shell size of ≤50 mm was a risk factor for malseating. Romero et al., in a retrospective radiographic review of 551 Stryker MDM shells that had been inserted at a single institution, found that 32 liners (5.8%) were malseated[47]. Those authors found that liners that had been inserted by low-volume surgeons were at increased risk for malseating[47]. An in vitro analysis that was part of that same report showed earlier

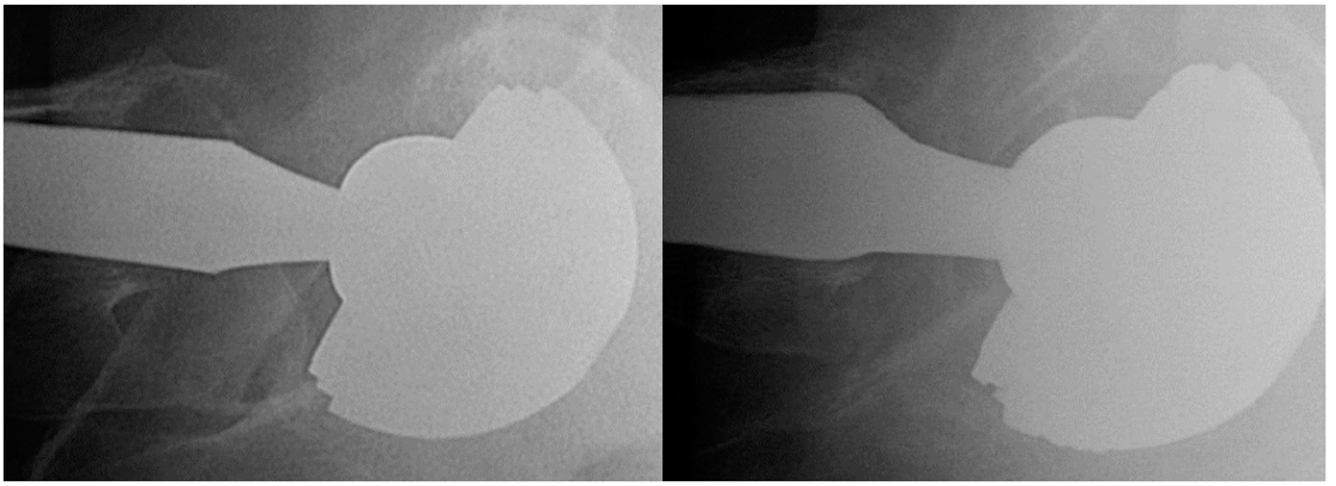

Fig. 5

On the left is a cross-table lateral image of a well-seated dual-mobility liner. On the right is a similar view of a malseated dual-mobility liner with a space visible at the posterior liner-shell interface. (Reprinted, with permission of The British Editorial Society of Bone & Joint Surgery, from: Romero J, Wach A, Silberberg S, Chiu YF, Westrich G, Wright TM, Padgett DE. 2020 Otto Aufranc Award: Malseating of modular dual mobility liners. Bone Joint J, 2020;102-B[7 Supple B]: 20-6. ©2020 The British Editorial Society of Bone & Joint Surgery.)

and increased fretting currents in malseated liners as compared with well-seated controls[47]. This finding lends credence to the concern that malseating may lead to increased rates of corrosion and adverse local tissue reactions. The authors recommended the cross-table lateral radiograph as a more effective way to diagnose DM liner malseating (Fig. 5).

Although malseating is sometimes clinically visible, allowing for immediate correction, the canting may only be prominent inferiorly, away from the surgeon's view. This explains why this "inferior" malseating pattern is most common[47]. Chalmers et al. recommended a complete 360° view of the shell prior to final liner implantation and a "4-quadrant test," using the impactor on the liner edge in 4 opposing points to check for toggling[48]. Chalmers et al. reported a malseating rate of 1.3% (4 of 305) in their single-surgeon series[48].

Corrosion and Adverse Local Tissue Reactions

Most modular DM constructs necessitate a cobalt-chromium liner engaging against a titanium shell. This dissimilar metal coupling has the potential for mechanically assisted crevice corrosion and adverse local tissue reactions (Fig. 6)[49]. This risk may be increased in cases of liner malseating, in which the process of mechanically assisted crevice corrosion is accelerated[47].

Kolz et al., in a retrieval analysis of 12 modular DM implants that had been in place for a mean of 26 months, reported that all retrieved implants demonstrated some degree of corrosive wear of the metallic liner[50]. All of the implants showed a maximum linear corrosive depth of >7 μm at the taper interface, albeit without any association with time in situ. Philippot et al., in another retrieval study involving the use of a roundness machine to assess for material loss, also found that liner-shell junctions

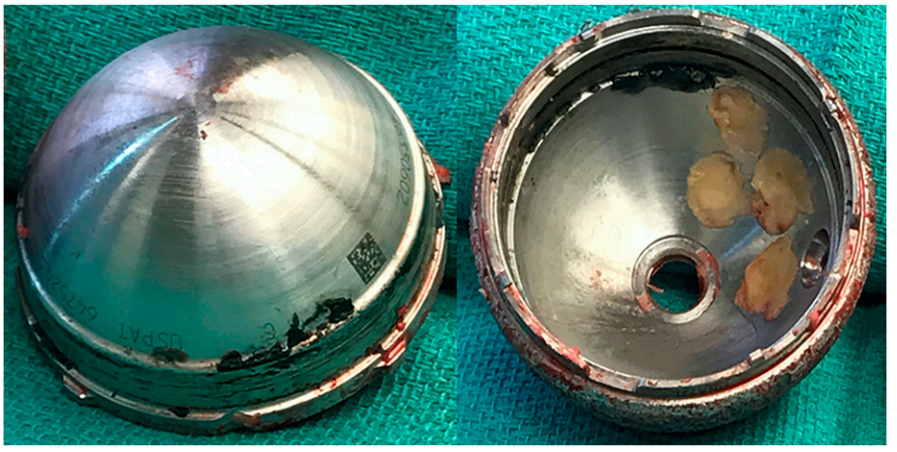

Fig. 6

Corrosion present on the backside surface of a modular cobalt-chromium liner retrieval. With (Reprinted from: Arthroplast Today, 6[4], Sonn KA, Meneghini RM, Adverse Local Tissue Reaction due to Acetabular Corrosion in Modular Dual-Mobility Constructs, 976-80, Copyright 2020.)

TABLE III Grades of Evidence for Recommendations Concerning Dual-Mobility Implants*

Recommendation	Grade
When possible, use monoblock instead of modular shells as these have the lowest shell-femoral head diameter difference and the least concern for corrosion.	B
In smaller modular dual-mobility constructs, the outer diameter of the polyethylene head is not much larger than the largest non-dual-mobility head option for that modular shell. In those scenarios, it is likely prudent to use the largest solid (non-dual-mobility) head and avoid the potential risk associated with modular dual mobility.	C
Obtain the exposure necessary to prevent malseating of modular liners to prevent an increase in corrosion.	C
Consider the use of ceramic 28-mm heads to limit the possibility of head-trunnion corrosion adding to the shell-liner interface corrosion.	C
Consider using general anesthesia rather than sedation when reducing a dislocated dual-mobility component to reduce the risk of intraprosthetic dislocation. Likewise, carefully scrutinize post-reduction radiographs, searching for signs of intraprosthetic dislocation.	I
Carefully monitor patients with modular dual-mobility implants for signs of corrosion and adverse local tissue reaction.	B

*Based on Wright[58], grade A indicates good evidence (Level-I studies with consistent findings) for or against recommending intervention; grade B, fair evidence (Level-II or III studies with consistent findings); grade C, poor-quality evidence (Level-IV or V studies with consistent findings); and grade I, insufficient or conflicting evidence not allowing a recommendation for or against intervention.

were a possible source of fretting corrosion and wear debris[38]. There also has been reporting on corrosion specifically between the cobalt-chromium liner and the abutting titanium screw heads[51]. This backside corrosion, although frequent, does not seem as prominent when compared with metal-on-metal modular liners[52].

Patients with modular DM constructs may have a greater prevalence of elevated metal ion levels[53]. Matsen Ko et al., in an investigation of 100 consecutive patients with a modular DM, reported that 21 patients had a reported serum cobalt above normal (with 9 having a substantially elevated level of >1.6 μg/L)[54]. Although the authors found an alternative explanation for the very high cobalt levels in 5 of those patients (e.g., other joint arthroplasty), 2 patients had magnetic resonance imaging findings that were suggestive of adverse local tissue reactions in the index hip.

In addition, there have been several case reports of revision surgery in which there was conclusive identification of corrosive changes in the liner-shell interface as the culprit for increased serum ion levels and adverse local tissue reactions[55,56] (Fig. 6).

Another potential site of corrosion of modular DM implants is between the cobalt-chromium liner and the side of the femoral trunnion. Impingement at the higher ranges of motion can lead to notching of the femoral trunnion that is visible on radiographs. Lygrisse et al., in a multicenter retrospective review, reported notching in association with 10 (4.9%) of 204 modular DM implants with a cobalt-chromium liner and a positive Charnley bore, compared with 0 of 84 monoblock DM shells or liners with an elevated rim[57].

The use of a 28-mm cobalt-chromium inner femoral head introduces an additional source of mechanically assisted crevice corrosion between the trunnion and the femoral head. Lombardo et al., in a retrieval study, reported fretting and corrosion changes at the trunnion-head interface as well as the shell-liner interface[51]. With respect to trunnion damage, there was no difference between stems used with monoblock DM components and stems used with modular DM components.

Gkiatas et al., in a systematic review of patients with DM components, reported that cobalt ions were elevated in 4 (3%) of 135 patients with ceramic femoral heads, compared with 9 (8%) of 113 patients with cobalt-chromium heads[53]. While the difference was not significant, this finding suggests that the use of ceramic heads with DM may be prudent.

Conclusions

DM may be beneficial for patients with a high risk of dislocation. Until more follow-up is available, surgeons should be judicious in their use of these implants. There are persistent concerns regarding the risk of corrosion that can occur between the liner and the modular acetabular shell. Recommendations based on existing data are listed in Table III. ■

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An Enhanced Understanding of Culture-Negative Periprosthetic Joint Infection with Next-Generation Sequencing

A Multicenter Study

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Background: The challenges of culture-negative periprosthetic joint infection (PJI) have led to the emergence of molecular methods of pathogen identification, including next-generation sequencing (NGS). While its increased sensitivity compared with traditional culture techniques is well documented, it is not fully known which organisms could be expected to be detected with use of NGS. The aim of this study was to describe the NGS profile of culture-negative PJI.

Methods: Patients undergoing revision hip or knee arthroplasty from June 2016 to August 2020 at 14 institutions were prospectively recruited. Patients meeting International Consensus Meeting (ICM) criteria for PJI were included in this study. Intraoperative samples were obtained and concurrently sent for both routine culture and NGS. Patients for whom NGS was positive and standard culture was negative were included in our analysis.

Results: The overall cohort included 301 patients who met the ICM criteria for PJI. Of these patients, 85 (28.2%) were culture-negative. A pathogen could be identified by NGS in 56 (65.9%) of these culture-negative patients. Seventeen species were identified as common based on a study-wide incidence threshold of 5%. NGS revealed a polymicrobial infection in 91.1% of culture-negative PJI cases, with the set of common species contributing to 82.4% of polymicrobial profiles. *Escherichia coli, Cutibacterium acnes, Staphylococcus epidermidis,* and *Staphylococcus aureus* ranked highest in terms of incidence and study-wide mean relative abundance and were most frequently the dominant organism when occurring in polymicrobial infections.

Conclusions: NGS provides a more comprehensive picture of the microbial profile of infection that is often missed by traditional culture. Examining the profile of PJI in a multicenter cohort using NGS, this study demonstrated that approximately two-thirds of culture-negative PJIs had identifiable opportunistically pathogenic organisms, and furthermore, the majority of infections were polymicrobial.

Level of Evidence: Diagnostic Level II. See Instructions for Authors for a complete description of levels of evidence.

The diagnosis and treatment of periprosthetic joint infection (PJI) following total joint arthroplasty remain a challenge. Pathogen identification is critical to making a definitive diagnosis and selecting targeted therapy; when no organism(s) can be found, the challenge is compounded. Current methods to identify the causative organisms in PJI rely on serological and synovial analysis using culture-based techniques. However, recent literature has demonstrated that culture fails to find an organism in up to 42% of infections[1-3]. In these cases of culture-negative PJI, the diagnosis is often questioned by both the patient and the treating physician, making it difficult to deliver targeted and effective antimicrobial therapy. Furthermore, while certain reports in the literature suggest that outcomes after culture-negative PJI are similar to those after PJI with an identifiable infecting organism, other work has found that the rate of recurrent infection and

Disclosure: The **Disclosure of Potential Conflicts of Interest forms** are provided with the online version of the article (http://links.lww.com/JBJS/H102).

reoperation is >4 times higher for culture-negative compared with culture-positive PJI, likely because of untargeted and ineffective treatment against the infecting pathogen[4].

Many factors likely contribute to the inadequacy of culture in identifying an organism in a high percentage of cases. One important factor may be the administration of antibiotics prior to sampling, which has been shown to significantly increase the risk of the inability to isolate infective organisms[2,5]. Recently it has been appreciated that an inability of microbes to form colonies on laboratory media does not necessarily rule out their ability to manifest their full potential as pathogens[6]. This phenomenon, originally described in 1982 by Xu and colleagues[7], and referred to as a viable but non-culturable (VBNC) state, has been shown to manifest in microbial communities as a consequence of local environmental stresses, such as exposure to antibiotics, and strong oxidants, such as chlorine and reactive oxygen species[8]. However, there are many other factors that are not patient- or treatment-dependent. Organisms causing infection in PJI often reside in a biofilm rather than in planktonic form, allowing the organisms to escape detection through traditional methods[9]. Culture is also highly user- and medium-dependent, with an undue reliance on both surgeon and laboratory personnel. Inadequate tissue sampling as well as improper or delayed handling and transport are likely factors in culture-negative results[2].

Quantitative polymerase chain reaction (qPCR) technology has garnered interest in recent years. Such assays are typically designed to detect specific species of microbes, and this species specificity is achieved by using primers that are complementary to DNA sequences unique to a given species. Early reports demonstrated high sensitivity of qPCR, particularly in its ability to detect organisms in a biofilm[10,11]. However, because qPCR assays by design are typically specific to a limited scope of microbes, global screening is achieved by other methods that utilize primers that are complementary to sequences that are conserved across diverse microbes, thus enabling their amplification and sequencing on next-generation sequencing (NGS) platforms. Microbial profiling using NGS has the potential to detect all pathogens present in a sample and has shown considerable promise in its diagnostic ability for the detection of infective organisms causing PJI[12,13]. The unbiased nature of NGS in comparison to culture or qPCR suggests that NGS may improve the detection and the identification of causative organisms in PJI. In fact, the American Academy of Microbiology has stated that NGS has the potential to be the single, all-inclusive diagnostic test that might transform traditional clinical microbiology[14].

NGS, therefore, holds great promise in the management of PJI. Its increased sensitivity is particularly valuable in the detection of infective organisms in culture-negative PJI. Prior single-center studies demonstrated the utility of NGS in culture-negative PJI using intraoperative tissue samples[12], and its concordance with culture using synovial fluid alone[13]. The aim of the current prospective study was to describe the profile of organisms detected by NGS in patients with culture-negative PJI and to corroborate prior work in a larger multi-institutional cohort. A comprehensive summary of the incidences and relative abundances of organisms from the overall cohort were also calculated, as was the frequency of polymicrobial detection and the tendency of specific organisms to exhibit numerical dominance across infections.

Materials and Methods

Following institutional review board approval, consecutive patients undergoing revision arthroplasty performed by surgeons at 14 participating institutions, during the period of June 2016 to August 2020, were prospectively enrolled in this study. All patients undergoing revision total knee or total hip arthroplasty were eligible for recruitment.

Preoperative Assessment

Patients undergoing revision arthroplasty were screened preoperatively according to institutional protocols, which included obtaining blood for measurement of the erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) level. Patients were aspirated at the discretion of the treating surgeon if it was believed that a definitive diagnosis had not been reached. In these cases, synovial fluid was assessed for white blood-cell count, white blood-cell differential, and leukocyte esterase (LE), and sent for culture.

Intraoperative Sample Collection

Synovial fluid, deep-tissue specimens, and swabs were obtained at the time of surgery. Synovial fluid was obtained in a sterile

TABLE I Demographics and Procedure Data*

Mean age *(yr)*	62.8
Mean BMI *(kg/m²)*	31.3
Mean CCI	3.0
Race/ethnicity *(no. [%])*	
White/Caucasian	66 (77.6%)
Black/African American	8 (9.4%)
Asian	2 (2.4%)
Unknown	9 (10.6%)
Joint *(no. [%])*	
Hip	29 (34.1%)
Knee	56 (65.9%)
Procedure *(no. [%])*	
2-stage revision	47 (55.3%)
Single-stage revision	23 (27.1%)
Irrigation and debridement	9 (10.6%)
Spacer exchange	5 (5.9%)
Above-the-knee amputation	1 (1.2%)

*BMI = body mass index, and CCI = Charlson Comorbidity Index.

fashion, using an 18-gauge needle prior to arthrotomy. Deep-tissue specimens were taken from the synovium and medullary canals. Swabs of the acetabulum and the medullary canal of the femur were obtained in the total hip arthroplasty cases, and swabs of the medullary canal of the femur and tibia were obtained in the total knee arthroplasty cases. The rationale for intraoperative swab sampling was based on our in vitro work demonstrating higher yield for biofilm sampling via molecular technologies. All samples were promptly transferred to sterile containers and shipped overnight at ambient temperature to the laboratory (MicroGenDX Laboratories) for NGS. Deep-tissue specimens were sent to the institutional laboratory for routine culture, including aerobic and anaerobic bacterial cultures, fungal cultures, and acid-fast bacilli cultures.

Next-Generation Sequencing

Variable regions 1 and 2 of the 16S ribosomal DNA gene were amplified and prepared into libraries for sequencing following molecular methods outlined by Tipton et al.[15] but using primers 28F and 388R, as reported by Tipton et al.[16]. Bioinformatic processing was the same as reported by Wolcott et al.[17]. Organisms present at <2.0% abundance were considered rare and were not included in summary analyses.

Source of Funding

No external funding was received for this study.

Results

Our overall cohort included 301 patients who met the 2018 International Consensus Meeting (ICM) criteria for PJI[18]. Of these patients, 216 had ≥1 positive culture and were thus excluded. Therefore, the rate of culture-negative PJI among the consecutive patients for whom NGS was utilized was 28.2% (85 of 301). This cohort of 85 patients included 56 patients with culture-negative PJI of the knee and 29 patients with culture-negative PJI of the hip. Forty-seven (55.3%) of the patients underwent 2-stage revision, 23 (27.1%) underwent single-stage revision, 9 (10.6%) had irrigation and debridement procedures, 5 (5.9%) underwent spacer exchange, and 1 (1.2%) of the patients underwent amputation (Table I).

A pathogen was identified in 56 (65.9%) of the 85 patients using NGS. An average of 1.7 samples per patient were NGS-positive, with 46.6% of the NGS-positive samples being tissue samples, followed by swabs (34.1%) and synovial fluid (19.3%). From the entire cohort, a total of 176 different species were identified by NGS, with 80 Gram-positive organisms, 84 Gram-negative organisms, and 12 fungi detected (see Appendix Supplementary Table 1). However, only 9.7% of the species (17 of 176) were considered common using a minimum 5% incidence as the threshold for defining common species. When ranked according to incidence across cases of culture-negative PJI, the most common species were *Escherichia coli, Cutibacterium acnes, Staphylococcus epidermidis,* and *S. aureus*. At the genus level, the most commonly detected organisms were

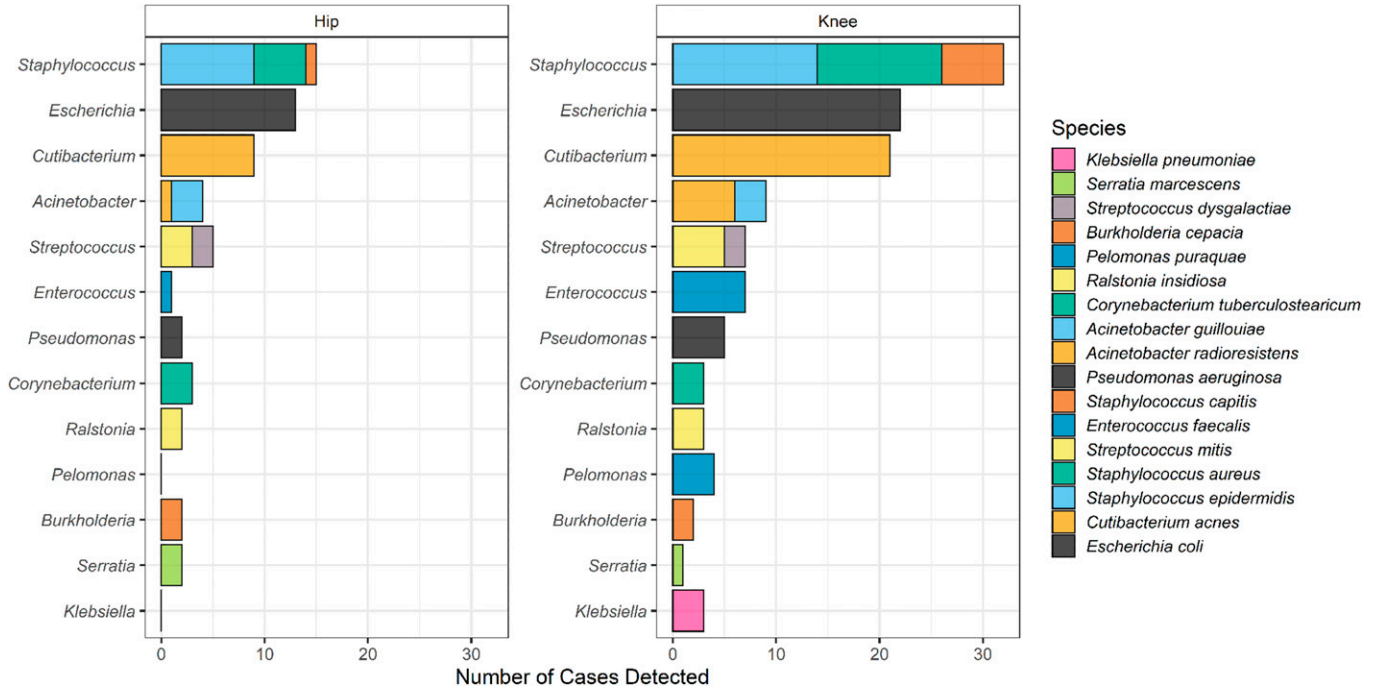

Fig. 1

Stacked bar plot of the number of cases detected (incidence) by microbial species and genera. Species are categorized by their respective genus for each bar. Genera are organized in the panels on the basis of incidence rates. Only species that were identified as common (having a minimum study-wide incidence of at least 5%) were included for plotting.

Staphylococcus, Escherichia, Streptococcus, Cutibacterium, and Acinetobacter (Fig. 1).

NGS revealed polymicrobial microbiota in 91.1% (51) of the 56 presumed culture-negative PJI cases. A median of 5 and a mean (and standard deviation) of 6.8 ± 5.1 different pathogens were identified per case (Fig. 2). Moreover, in 82.4% (42) of the 51 polymicrobial cases, multiple species defined as common (on the basis of a 5% incidence threshold) were present; a median and mean of 3 and 3.2 ± 2.2 common species, respectively, were present in these cases. In each polymicrobial case, 1 organism was identified as dominant on the basis of having the highest relative abundance. Not only did *E. coli, C. acnes, S. epidermidis,* and *S. aureus* rank the highest for incidence and study-wide mean relative abundance, but they were also found most frequently to be the dominant organism when occurring in polymicrobial infections (Fig. 3).

Discussion

It is imperative to identify pathogens causing an infection in general, and PJI in particular, in order to facilitate a targeted approach of antimicrobial therapy. Recent studies have demonstrated the promising role of molecular techniques in helping to address the selection of effective antimicrobial therapeutic strategies. NGS, which is technically capable of sequencing all of the nucleic acid present in a given sample, has been shown to provide a comprehensive picture of the microbial profile that traditional cultures may miss[9]. In recent years, with advances in the speed of bioinformatic processing in concert with a substantial decrease in the cost of sequencing, this approach has become clinically feasible. The clinical application of NGS is becoming widespread as pathogens responsible for recalcitrant infections are being identified and effectively treated. Examples of valuable clinical information provided by NGS are rapidly accumulating and include the identification of *Abiotrophia defectiva* in culture-negative endocarditis[19] and neuroleptospirosis in culture-negative meningitis[20]. Prior single-institution data have demonstrated that NGS is a useful adjunct to routine culture, with pathogens being identified in 81.8% of culture-negative PJI cases[12] and with a high concordance between NGS and traditional culture in culture-positive cases[13]. Recently, other studies investigating the utility of metagenomic sequencing of sonicated synovial fluid have further confirmed the utility of sequencing-based approaches. A 2017 study by Street et al.[21] found 88% species-level sensitivity using this methodology. Similarly, in a 2018 report, Thoendel et al.[22] identified a pathogen in 94.8% of culture-positive and 43.9% of culture-negative PJI cases.

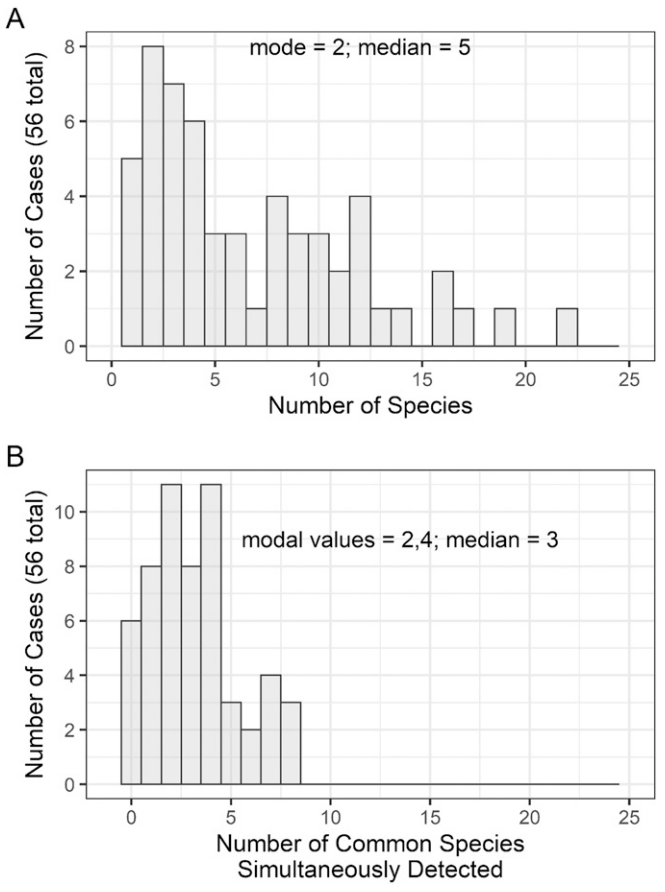

Fig. 2

Frequency distributions for the number of species detected per case.

Fig. 2-A The distribution for all species detected with ≥2% relative abundance in a sample. **Fig. 2-B** Distribution only for species characterized as common on the basis of having a study-wide incidence of at least 5%.

While recent literature has shown the utility of NGS specifically within the setting of culture-negative PJI, most prior studies are limited in size because of the relative rarity of PJI. The intention of the current multicenter, prospective study was to examine the profile of organisms detected by NGS in culture-negative PJI cases. The data collected in this study demonstrate that approximately two-thirds of culture-negative PJIs had an identifiable organism using NGS. Our results revealed the increased sensitivity of NGS for revealing the identity of VBNC microbes in culture-negative PJI cases and providing a treatment team with a profile of the types of microbes that warrant consideration as they develop their treatment plan for the patient.

In the overwhelming majority (91.1%) of culture-negative PJI cases, NGS data implied that the PJI was polymicrobial in nature, with 2 organisms being the number of species most commonly detected from each patient (median, 5 species; mean, 6.8 organisms; and mode, 2 species per case). Moreover, most joints were multiply colonized by a subset of common species characterized as having high incidence, relative abundance, and a tendency to dominate the periprosthetic infections identified. Our findings are consistent with prior studies suggesting that PJIs are most often polymicrobial, when the community is assessed using microbial DNA as the census instrument[12,21,22]. This is in contrast to the established understanding of PJI based on traditional culture methodology[9].

There are several, not necessarily mutually exclusive, explanations as to why presumed culture-negative PJIs do, in fact, contain microbes, and often in a polymicrobial state: (1) the organisms are in low abundance, such that they are below

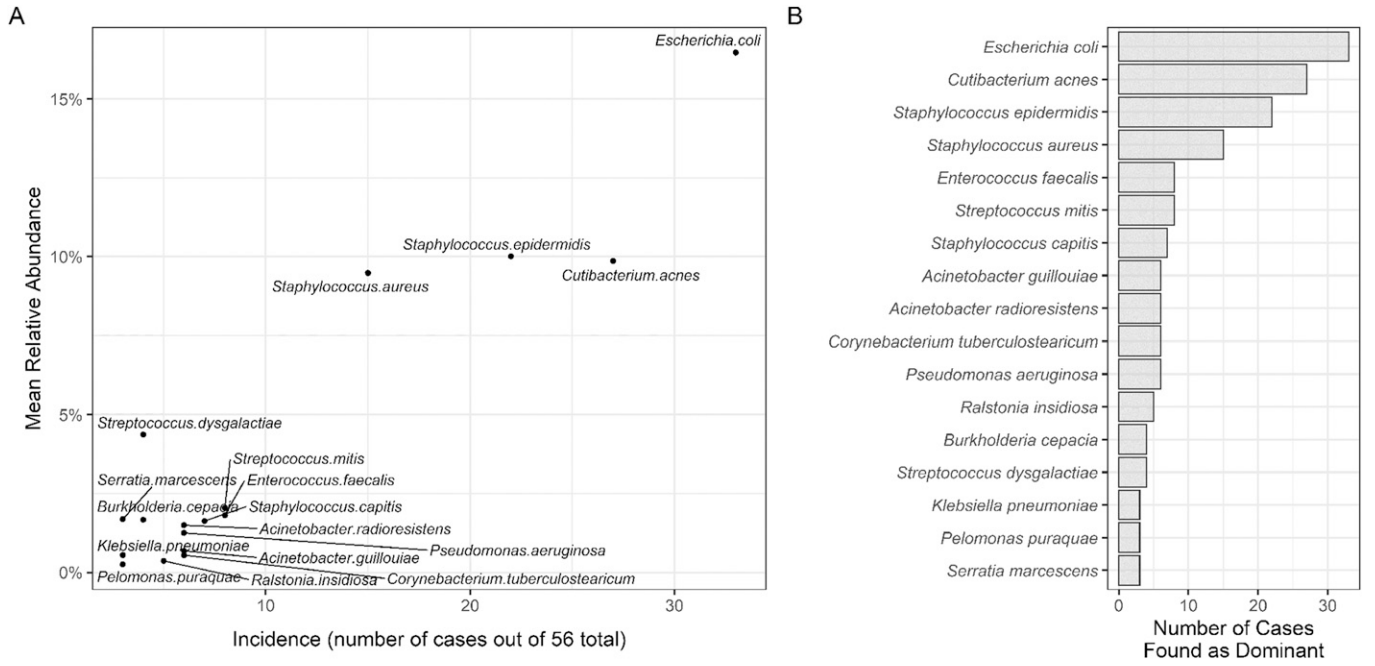

Fig. 3

Trends in species incidence and prevalence, summarized by the relationship between incidence and study-wide mean relative abundance (**Fig. 3-A**) and counts of the number of cases in which the listed species were numerically dominant (**Fig. 3-B**). Only species that were identified as common on the basis of having a minimum study-wide incidence of at least 5% were included for plotting.

the sensitivity limits of routine culture; (2) the organisms are in a VBNC state and yet can still manifest symptoms of an infection in the patient; (3) the organisms are fastidious and not in a planktonic state, reducing their ability to be detected by routine culture; (4) the culture media used may not be suitable for the growth of the organisms present in the sample; and (5) the multiple organisms may compete against each other in the medium, making the isolation of all pathogens by routine culture difficult.

It is plausible that the majority of infections, not just those that are culture-negative, are polymicrobial in nature, as microbes commonly exist in functionally interacting communities. Other work regarding chronic wound infections has shown that most are polymicrobial, and that the polymicrobial composition is consequential to healing[16,23]. This polymicrobial theory may explain why organisms isolated at the time of arthroplasty failure are sometimes different from the initial organism(s) causing the infection and those detected by routine culture[24]. Temporal succession of polymicrobial communities in infection has been previously described[23,25].

The genus most often found to dominate joints in our cohort was Staphylococcus, with *S. epidermidis* and *S. aureus* being the most common species. This is of particular relevance in light of literature investigating the course of culture-negative infections. In a 2019 report, Hersh et al.[26] followed 36 culture-negative PJI cases and found that, in 5 of 8 irrigation and debridement procedures that later failed because of reinfection, Staphylococcus species (both *S. aureus* and coagulase-negative staphylococci) were the pathogens responsible for failure of treatment. While that study included a relatively small number of patients, it demonstrated the relevance of NGS positivity in culture-negative PJI. Future research should investigate the correlation of NGS signal found in these cases to the organism causing failure in the same cohort of patients.

Our study had limitations. Without correlating the NGS signal to longitudinal clinical follow-up and outcomes, the interpretation of NGS results remains uncertain. The cohort in this multicenter study is, however, being followed as a separate research endeavor. In particular, further work needs to address how physicians should treat positive signals for organisms across multiple specimens per patient. Despite our numerous efforts at quality control and standardization, the potential for contamination and differences in sampling methodology, transport duration, and reporting thresholds may all impact the relevance of positive NGS results. Furthermore, the clinical importance of the NGS signal seen in primary osteoarthritic joints in prior studies also remains to be determined, as does whether it represents a dysbiotic osteoarthritic microbiome or unaccounted-for contamination encountered along the pipeline. Tarabichi et al.[12] found concordance between NGS and the culture-identified pathogen in many but not all cases of PJI. The source and interpretation of discrepancies between NGS and culture must be further elucidated before NGS can be a standard tool in PJI diagnostics. In our study, we considered a dominant organism as having the highest percent abundance, as measured by nucleic acid across all samples. However, most patients had multiple samples, and it would also be reasonable to account for the number of positive samples for a given

organism in determining its dominance. The optimal approach is likely a combination, but our study was not formally set up to make such a determination.

In conclusion, culture-negative PJI was often associated with a polymicrobial genomic organism profile. Our findings suggest that many cases of PJI may be polymicrobial and may escape detection using conventional culture. The results of this collaborative research endeavor, involving multiple academic centers and, to our knowledge, the largest number of patients in studies investigating NGS in orthopaedics, support the utility of NGS in the diagnosis of complex orthopaedic infections, in particular in the setting of culture-negative PJI.

Key questions remain, such as how we move from traditional culture techniques to the more expansive data regarding the polymicrobial nature of PJI characterized by NGS. A corollary question relates to antibiotic choice and whether broad-spectrum antibiotics are necessary in all patients with PJI. Formal randomized trials and multi-institutional work including clinical follow-up are ongoing to further investigate these issues.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H103). ■

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Is the Revision Rate for Femoral Neck Fracture Lower for Total Hip Arthroplasty Than for Hemiarthroplasty?

A Comparison of Registry Data for Contemporary Surgical Options

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Background: When arthroplasty is indicated for a femoral neck fracture (FNF), it is unclear whether total hip arthroplasty (THA) or hemiarthroplasty (HA) is best. This study compares data from the Australian Orthopaedic Association National Joint Replacement Registry using contemporary surgical options.

Methods: Patients from 60 to 85 years old who were treated with arthroplasty for FNF, between September 1999 and December 2019, were included if the femoral stems were cemented. Only THAs with femoral heads of ≥36 mm or dual-mobility articulations were included. Patients who had monoblock HA were excluded. Rates of revision for all aseptic failures and dislocation were compared. Competing risks of revision and death were considered using the cumulative incidence function. Subdistribution hazard ratios (HRs) for revision or death from a Fine-Gray regression model were used to compare THA and HA. Interactions of procedure with age group and sex were considered. Secondary analysis adjusting for body mass index (BMI) and American Society of Anesthesiologists (ASA) classification was also considered.

Results: There were 4,551 THA and 29,714 HA procedures included. The rate of revision for THA was lower for women from 60 to 69 years old (HR = 0.58 [95% confidence interval (CI), 0.39 to 0.85]) and from 70 to 74 years old (HR = 0.65 [95% CI, 0.43 to 0.98]) compared with HA. However, women from 80 to 85 years old (HR = 1.56 [95% CI, 1.03 to 2.35]) and men from 75 to 79 years old (HR = 1.61 [95% CI, 1.05 to 2.46]) and 80 to 85 years old (HR = 2.73 [95% CI, 1.89 to 3.95]) had an increased rate of revision when THA was undertaken compared with HA. There was no difference in the rate of revision for dislocation between THA and HA for either sex or age categories.

Conclusions: When contemporary surgical options for FNF are used, there is a benefit with respect to revision outcomes for THA in women who are <75 years old and a benefit for HA in women who are ≥80 years old and men who are ≥75 years old. There is no difference in dislocation rates.

Level of Evidence: Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

When arthroplasty is indicated for femoral neck fractures (FNFs), is a patient better served by total hip arthroplasty (THA) or hemiarthroplasty (HA)? The available literature is helpful but inconclusive[1]. The decision is complex, as one option might be preferred on the basis of patient-related factors[2-8], such as age, activity level, and risk of complications, or surgeon preference or expertise[9-11]. Although more patients with FNF undergo HA, a cohort who live independently, are without dementia, and are of appropriate age and life expectancy may be managed with THA or HA[1].

HA is generally regarded as a quicker, less complex[9], and less expensive surgery. Randomized controlled trials (RCTs) have described higher reoperation rates after HA for FNF compared with those after THA[12-19], although patients who had THA had higher dislocation rates[14,16,18,20-23]. THA may permit higher levels of patient function[2,14,15,20,24], particularly after longer follow-up[24-28] and in younger patients[28,29].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H138).

Previous studies of arthroplasty for FNF have compared all implant designs and modes of fixation, which include poorly performing prostheses and implants with known higher revision rates that would appropriately be excluded from contemporary practice. This includes monoblock (nonmodular) HA[2,17,30-35], cementless femoral stems in both THA[2,36-41] and HA[35,42-46], and small femoral heads in THA[47]. Large femoral head sizes (≥36 mm) for the treatment of FNF have been shown to significantly reduce the rate of revision for dislocation compared with small sizes of femoral heads[48]. Dislocation is the reason why many surgeons choose HA over THA for FNF[49].

Published RCTs comparing HA and THA for FNF have included relatively short durations of follow-up[23], which affects outcome[15], and adequate studies are lacking in public health systems[50]. Registry data can provide more accurate conclusions if underperforming implants are excluded, if confounding variables are controlled, and if patients with equivalent life expectancies are compared. The present study used data from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) to compare contemporary THA and HA implants used for FNF with respect to revision rates for all aseptic causes and specifically for dislocation.

Materials and Methods

The AOANJRR includes information on 98% of arthroplasties performed. Registry data are validated against patient-level data provided by each state and territory health department with the use of a sequential, multilevel matching process. A matching program is run monthly to search for all primary and revision procedures recorded in the registry that involved the same side and joint for the same patient, enabling each revision to be linked to the primary procedure. Data are matched by the National Death Index of the Australian Institute of Health and Welfare to obtain information on the date of death.

The study included THA and HA procedures performed for a diagnosis of FNF in patients from 60 to 85 years old that were reported to the AOANJRR from September 1, 1999, to December 31, 2019. Inclusion criteria for THAs were polished cemented femoral stems using only femoral head sizes of ≥36 mm or dual-mobility (DM) bearings with highly cross-linked polyethylene (XLPE) and a metal or ceramic femoral head. Exclusion

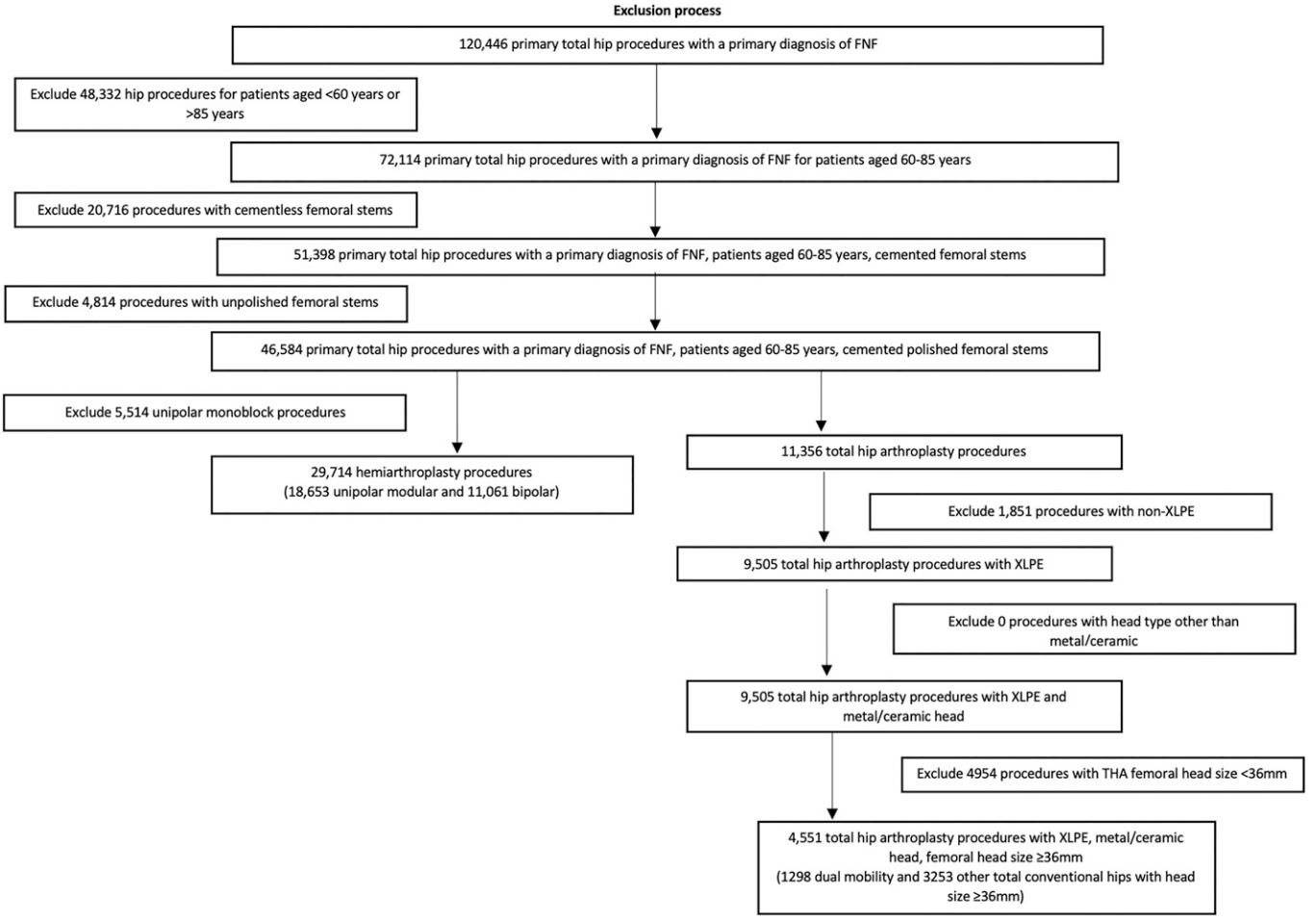

Fig. 1

Exclusion process. FNF = femoral neck fracture, XLPE = highly cross-linked polyethylene, and THA = total hip arthroplasty.

criteria were cementless femoral fixation, matte-finished cemented stems, femoral head sizes of <36 mm, constrained acetabular liners, non-XLPE, and metal-on-metal or ceramic-on-ceramic bearing surfaces. Inclusion criteria for HA were smooth, polished cemented femoral fixation using unipolar or bipolar bearings. Exclusion criteria were cementless femoral fixation, matte-finished cemented stems, and monoblock prostheses.

The primary outcome measure was revision for all aseptic causes (excluding infection). The secondary outcome measure was revision for dislocation. The model included hip class (THA or HA), age group (60 to 69, 70 to 74, 75 to 79, and 80 to 85 years), and sex, and their interactions. The American Society of Anesthesiologists (ASA) score and body mass index (BMI) were included as confounders in secondary analysis as data for these predictors were only available since 2015.

Statistical Analysis

The time to the first revision was described using Kaplan-Meier estimates of survivorship, with right-censoring for death or closure of the database at the time of analysis for the purpose of this study. The unadjusted (raw) cumulative percent revision and 95% confidence interval (CI) were estimated. Hazard ratios (HRs) from Cox proportional hazard models were used to compare the rate of revision between HA and THA. The assumption of proportional hazards was checked analytically for each model. If the interaction between the predictor and the log of time was significant in the standard Cox model, then a time-varying model was estimated. Time points were iteratively chosen until the assumption of proportionality was met, and the HRs were calculated for each selected time period. In the results, if no time period was specified, then the HR was

TABLE I Summary of Data on Femoral Cemented Primary Hip Replacements (for a Primary Diagnosis of FNF)*

Variable	THA (N = 4,551)	HA (N = 29,714)	Total (N = 34,265)
Duration of follow-up *(yr)*			
Mean and SD	3.3 ± 2.9	3.7 ± 3.6	3.6 ± 3.6
Median (IQR)	2.5 (1, 4.8)	2.6 (0.8, 5.4)	2.5 (0.8, 5.3)
Minimum	0	0	0
Maximum	16.1	20.2	20.2
Age *(yr)*			
Mean and SD	74.2 ± 6.9	78 ± 6	77.5 ± 6.2
Median (IQR)	75 (69, 80)	80 (75, 83)	79 (74, 83)
Sex			
Male	1,735 (38.1%)	9,070 (30.5%)	10,805 (31.5%)
Female	2,816 (61.9%)	20,644 (69.5%)	23,460 (68.5%)
Age group			
60-69 yr	1,246 (27.4%)	3,273 (11.0%)	4,519 (13.2%)
70-74 yr	957 (21%)	4,120 (13.9%)	5,077 (14.8%)
75-79 yr	1,101 (24.2%)	7,453 (25.1%)	8,554 (25.0%)
80-85 yr	1,247 (27.4%)	14,868 (50.0%)	16,115 (47.0%)
BMI†			
Underweight	88 (4.6%)	526 (8.2%)	614 (7.4%)
Normal	785 (40.7%)	2,980 (46.5%)	3,765 (45.1%)
Preobese	687 (35.6%)	1,935 (30.2%)	2,622 (31.4%)
Obese class 1	266 (13.8%)	688 (10.7%)	954 (11.4%)
Obese class 2	85 (4.4%)	204 (3.2%)	289 (3.5%)
Obese class 3	20 (1%)	75 (1.2%)	95 (1.1%)
ASA score‡			
1	111 (3.2%)	59 (0.4%)	170 (0.9%)
2	1,379 (39.8%)	2,191 (14.4%)	3,570 (19.1%)
3	1,717 (49.5%)	9,484 (62.4%)	11,201 (60%)
4	259 (7.5%)	3,442 (22.6%)	3,701 (19.8%)
5	3 (0.1%)	30 (0.2%)	33 (0.2%)

*THA = total hip arthroplasty, HA = hemiarthroplasty, FNF = femoral neck fracture, SD = standard deviation, IQR = interquartile range, BMI = body mass index, and ASA = American Society of Anesthesiologists. †Excludes 25,926 procedures in patients with unknown BMI. ‡Excludes 15,590 procedures in patients with unknown ASA score.

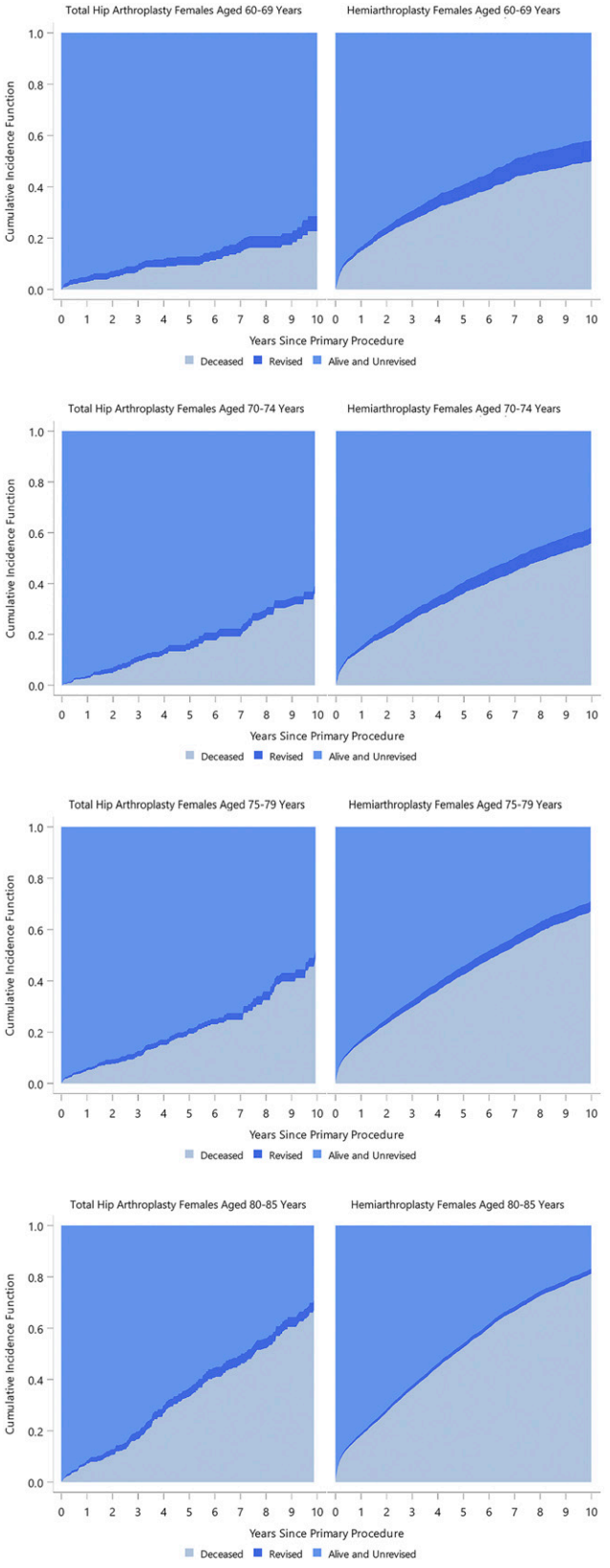

Fig. 2

The cumulative incidence function of primary hip replacement with a femoral cemented stem in female patients in age groups from 60 to 69 years, 70 to 74 years, 75 to 79 years, and 80 to 85 years by procedure (primary diagnosis: femoral neck fracture, revision: excluding infection).

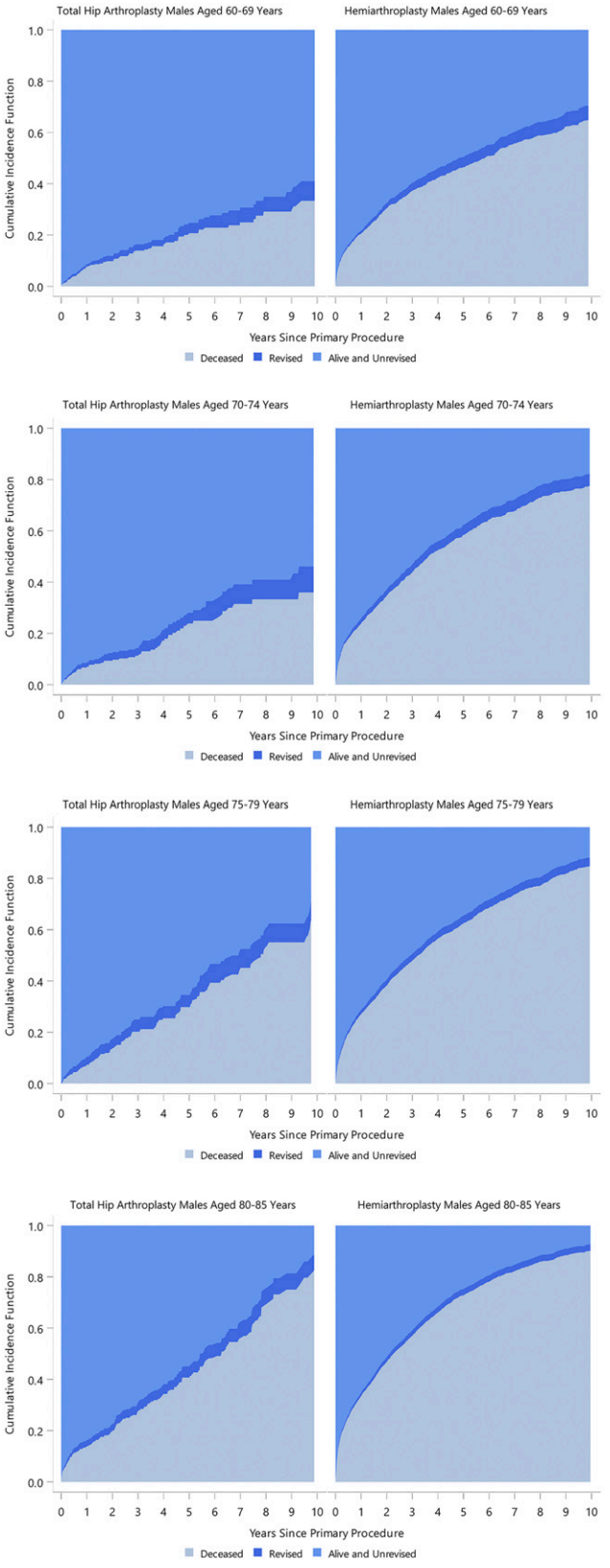

Fig. 3

The cumulative incidence function of primary hip replacement with a cemented femoral stem in male patients in age groups from 60 to 69 years, 70 to 74 years, 75 to 79 years, and 80 to 85 years by procedure (primary diagnosis: femoral neck fracture, revision: excluding infection).

TABLE II Hazard Ratios and Subdistribution Hazard Ratios for THA Revision for All Aseptic Causes*

Sex	Age Group *(yr)*	HR (95% CI)	Subdistribution HR (95% CI)
Female	60-69	0.57 (0.37, 0.89)	0.58 (0.39, 0.85)
	70-74	0.48 (0.27, 0.87)	0.65 (0.43, 0.98)
	75-79	0.67 (0.39, 1.16)	0.92 (0.62, 1.36)
	80-85	1.70 (1.08, 2.68)	1.56 (1.03, 2.35)
Male	60-69	0.78 (0.45, 1.35)	1.01 (0.68, 1.52)
	70-74	1.11 (0.64, 1.92)	1.13 (0.72, 1.79)
	75-79	1.52 (0.91, 2.53)	1.61 (1.05, 2.46)
	80-85	1.62 (0.99, 2.64)	2.73 (1.89, 3.95)

*All hazard ratios (HRs) are for total hip arthroplasty (THA) versus hemiarthroplasty. CI = confidence interval.

proportional over the entire follow-up period. As the Kaplan-Meier method is known to overestimate the probability of revision when the risk of death is high, we performed modeling with competing risks for which we estimated the probability of revision and considered death as a competing risk using the cumulative incidence function. Subdistribution HRs from a Fine-Gray regression model were used to compare the rate of both revision and death as outcomes. All tests were 2-tailed at the 5% level of significance. Analysis was performed using SAS version 9.4 (SAS Institute).

Source of Funding
No funding was used for this study.

Results

There were 4,551 THAs and 29,714 HAs performed for FNF that met the inclusion criteria (Fig. 1). THA was performed in younger patients (mean age, 74.2 versus 78.0 years, respectively), with higher BMI (mean, 27.2 versus 25.0 kg/m^2), and in fewer women (61.9% versus 69.5%) (Table I). The THA group included 1,298 DM constructs (28.5%) and 3,253 (71.5%) femoral heads ≥36 mm in diameter. The HA group included 18,653 hips (62.8%) with unipolar bearings and 11,061 hips (37.2%) with bipolar bearings.

Unadjusted Kaplan-Meier estimates and the cumulative incidence for each sex and age group for the outcomes of revision and death were calculated (Figs. 2 and 3 and Appendix Supplementary Tables 1 and 2). The cause-specific HRs from the Cox model and the subdistribution HRs from the Fine-Gray models for revision are presented in Table II. The cause-specific HRs from a Cox model for revision indicated that there were interactions of procedure with both age group and sex. Younger women, i.e., those who were <75 years old, had a significantly lower risk of revision in the THA group than those in the HA group (HR = 0.58 [95% CI, 0.39 to 0.85] for those from 60 to 69 years old, and HR = 0.65 [95% CI, 0.43 to 0.98] for women from 70 to 74 years old). Older women, i.e., those from 80 to 85 years old, had a high rate of revision in the THA group compared with that in the HA group (HR = 1.56 [95% CI, 1.03 to 2.35]). The results were similar for the Fine-Gray approach. Older men, i.e., those ≥75 years old, had a higher rate of revision in the THA group compared with those in the HA group (HR = 1.61 [95% CI, 1.05 to 2.46] for men from 75 to 79 years old, and HR = 2.73 [95% CI, 1.89 to 3.95] for those from 80 to 85 years old). This effect is also evident using the Fine-Gray model, which allows for the competing risk of death.

In the analysis with adjustment for BMI and ASA, only data from 2015 onward were included. There was a significant interaction between sex and procedure. Age was not a risk factor in a comparison of the 2 classes of joint replacement. For women, there was no difference in the rate of revision in a comparison of THA and HA for the Cox regression model and Fine-Gray approaches (HR = 0.68 [95% CI, 0.39 to 1.17], and subdistribution HR = 0.73 [95% CI, 0.42 to 1.28]). After accounting for the competing risk of death, men had a higher rate of revision when undergoing THA compared with HA (HR = 1.50 [95% CI, 0.89 to 2.54] and subdistribution HR = 1.77 [95% CI, 1.04 to 3.01]).

The reason for THA revision in women differed for each age category, with the leading causes of revision overall being dislocation, followed by fracture and component loosening (Fig. 4). Revisions in men were predominantly due to periprosthetic fracture, followed by component loosening and dislocation (Fig. 5). For HA, the reasons for revision for both sexes were chondrolysis or acetabular erosion and pain in patients who were <80 years old, followed by fracture, component loosening, and dislocation. Chondrolysis or acetabular erosion was more prevalent in patients who were <75 years old.

Revision for Dislocation

With revision for dislocation as the outcome, there were no interactions of age group and/or sex with procedure. The main effect of the procedure was also not significant, indicating there was no difference in the risk of revision for dislocation if THA was undertaken compared with HA. This was true for the Cox regression and Fine-Gray approaches (HR = 1.20 [95% CI, 0.86 to 1.68] and subdistribution HR = 1.28 [95% CI, 0.92 to 1.80] for THA versus HA).

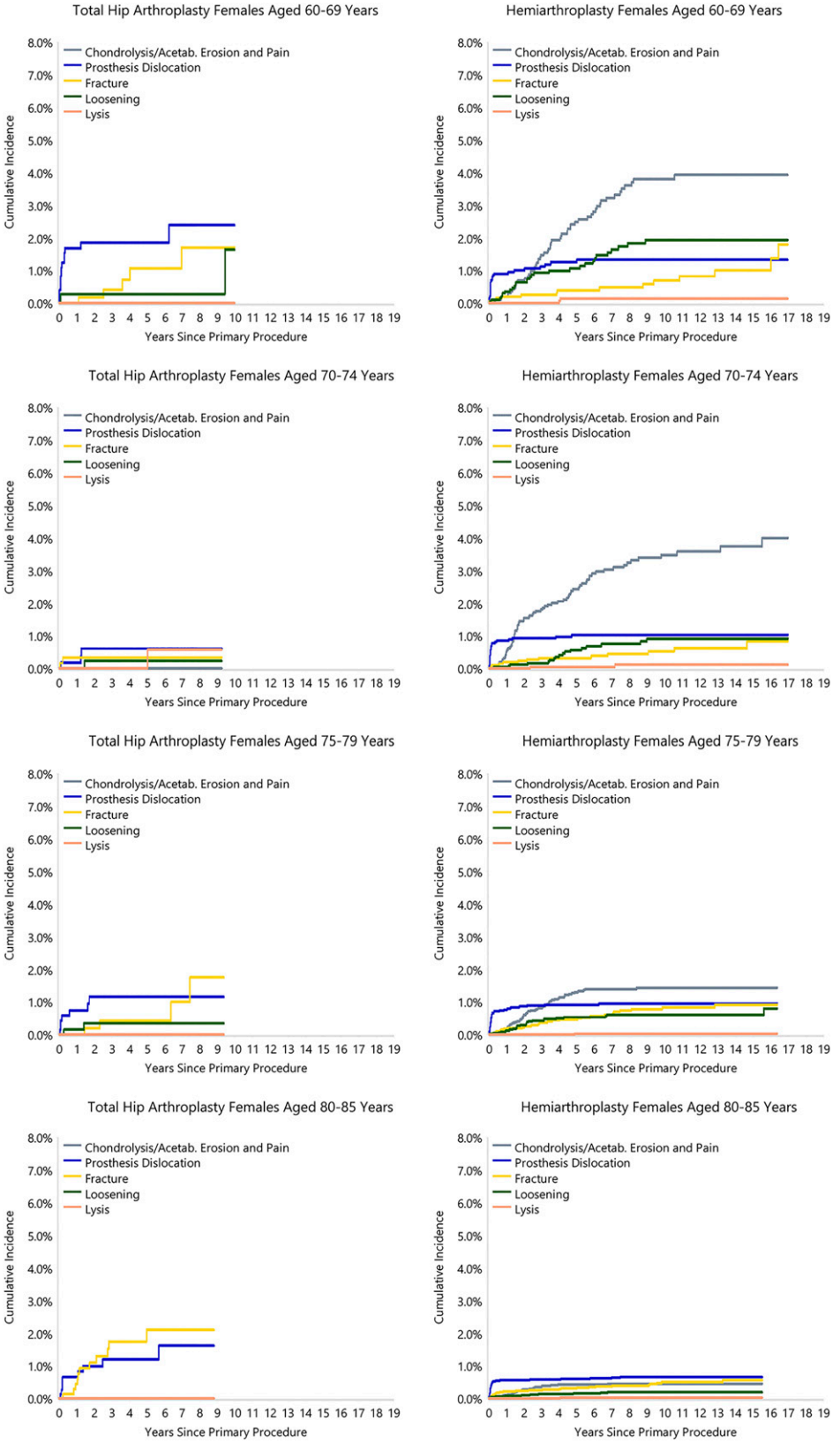

Fig. 4

The cumulative percent of revision diagnoses after primary hip replacement with a cemented femoral stem in female patients from 60 to 85 years old by procedure (primary diagnosis: femoral neck fracture, revision: excluding infection).

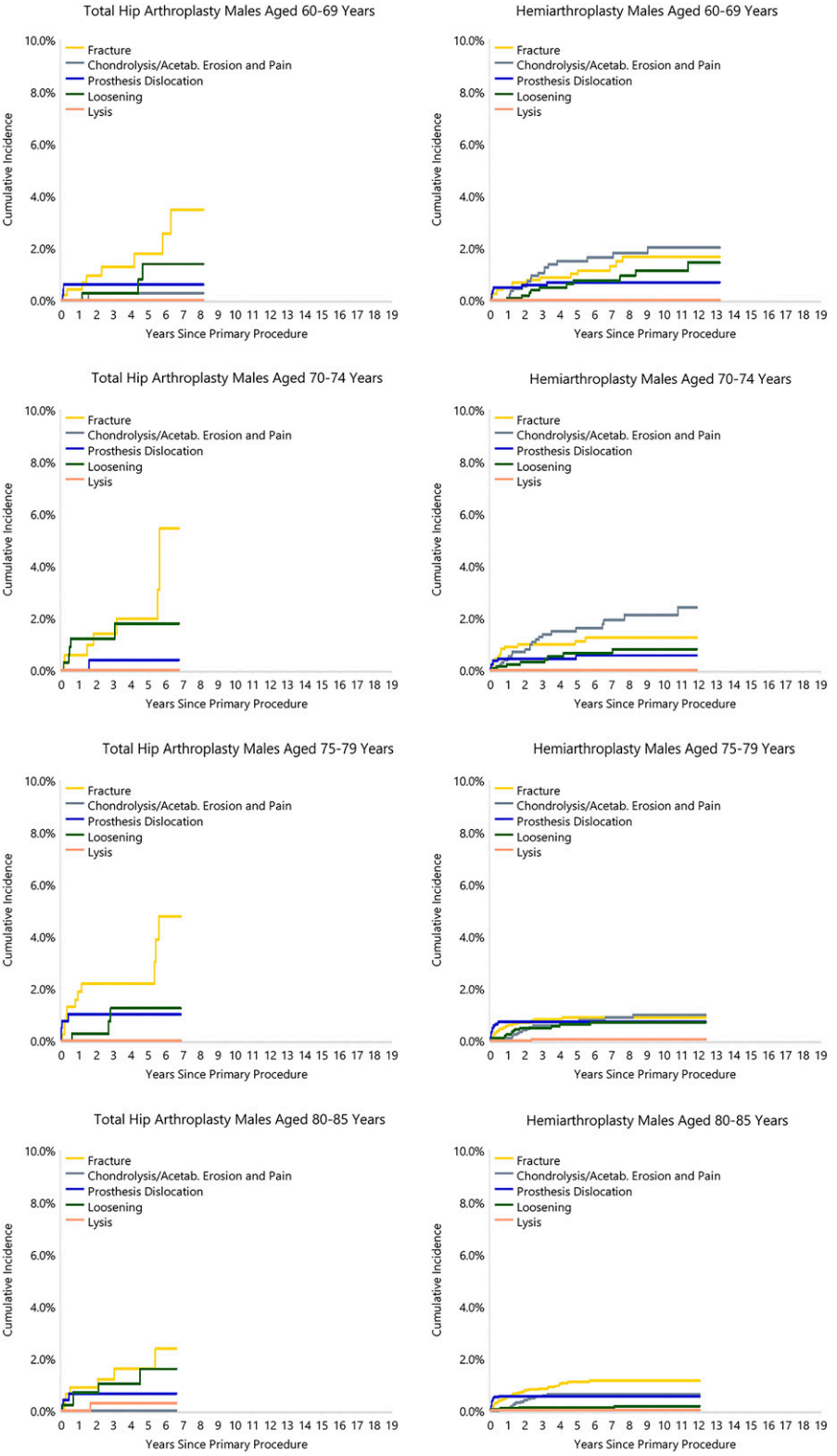

Fig. 5

The cumulative percent of revision diagnoses after primary hip replacement with a cemented femoral stem in male patients from 60 to 85 years old by procedure (primary diagnosis: femoral neck fracture, revision: excluding infection).

Discussion

This large national registry study demonstrates that when contemporary surgical options for THA and HA are compared as treatment for FNF, using models that allow for the competing risk of death and adjusting for confounders, there is a significant benefit for THA in women who are <75 years old and a significant benefit for HA in women who are ≥80 years old and men who are ≥75 years old. Total hip replacements were predominantly revised for periprosthetic fracture, followed by component loosening and dislocation. The predominant cause of HA revision was chondrolysis or acetabular erosion and pain, particularly in younger patients. We excluded patients with uncemented femoral stem fixation to remove the potential confounding with this surgical decision. There was no difference between THA and HA for dislocation.

Our results, which showed a benefit in terms of aseptic revisions for THA in younger women and a benefit for HA in older women and men, are not consistent with a meta-analysis of RCTs that found no differences between THA and HA at the 5-year follow-up[51] or in the largest and most recent RCT with 2 years of follow-up[23]. By contrast, other meta-analyses have supported our results in part and have found that THA had lower revision rates than HA[52,53]. The main limitations of many RCTs and meta-analyses are the limited duration of follow-up and broad implant options that may not be used or should not be used in modern practice. Complications increase with the duration of follow-up after arthroplasty for FNF[15]. This may explain findings that are different from those in our study.

Chondrolysis or acetabular erosion and pain was the leading cause of aseptic revision for HA, especially in patients who were <75 years old, and was more prominent in women. THA for FNF has been favored for some patients from 60 to 75 years old for this reason[54], but life expectancy rather than chronological age may be key. One meta-analysis recommended THA for patients younger than 80 years with a life expectancy of >4 years[52]. We performed a subanalysis of the results by sex and stratified by age, given the known differences in life expectancy for women and men. Scoring systems can help in deciding between THA and HA[6] and in predicting the short-term risk of death[55,56], but none currently predict 5-year mortality. The mean age of patients with an FNF is 80 years[57]. Some younger patients, women in particular, experience a benefit with THA. Future research must predict long-term patient survival to improve patient selection for THA.

THA and HA performed for FNF should improve with better implants, as determined by registry outcomes. Our study differs from current literature in comparing only contemporary surgical options for THA and HA supported by published literature. We limited femoral implants to those with smooth, polished cemented stems[58], excluding cementless stems. Femoral component loosening is the main reason for revision of HAs treating FNF when cementless and cemented femoral stems are compared in registries[35]. Cemented stems have superior outcomes in multiple studies for both THA[36-41] and HA[35,42-46] for FNF. We excluded monoblock HAs, given their higher rates of revision[2,17,30-34]. This explains, at least in part, why our results differ from those in other reports and the extremely low rates of revision for component loosening in our study.

Our results showing no difference in revision for dislocation agree with 1 meta-analysis of RCTs[51], but differ from the largest and most recent RCT[23], 1 national data set[53], and other meta-analyses that have shown clear significance[52,59], or approaching significance, for an increased rate of dislocation with THA[53]. Those studies included all THA femoral head sizes, including smaller diameters that may be associated with dislocation. If these underperforming options are removed from practice, patient outcomes should reflect the findings of our investigation. To our knowledge, no RCT that has described dislocation rates has been restricted to femoral head diameters of ≥36 mm and/or DM bearings. Compared with femoral head sizes of ≤32 mm, large-diameter head sizes have a significant reduction in revision surgery for dislocation in patients with FNF[48]. The largest RCT included 36-mm head sizes but did not compare dislocation rates with 32-mm femoral heads[23]. Other RCTs have not specified the head size used[28,29] or have included 32-mm[60] or 28-mm femoral heads[12,13,25-27]. Male patients are more likely to have an acetabular component size that accommodates a large femoral head, and this may explain the slightly higher percentage of THAs performed in men, given our inclusion criteria. Systematic reviews have concluded that DM bearings are equivalent, or superior, to large femoral bearings in reducing the risk of dislocation in primary and revision surgery[61-64] and have a lower risk of dislocation and revision than HA[65]. Systematic reviews have supported the use of DM bearings as a viable option for FNF[66]. Despite our exclusion criteria, dislocation remained a prominent cause of revision following THA, particularly for women, and also following HA, highlighting the high risk of dislocation in patients with FNF. Our inclusion and exclusion criteria could be applied to future RCTs. However, given the difficulty and expense of performing adequately powered RCTs[67] and the reliability of registry data[53], these studies may not be necessary before standard practice evolves. Nested RCTs utilizing registry data may be the best study design.

There are limitations to the current study. Groups were not matched for age, sex, ASA, and BMI, and a disparity existed for mortality with respect to implant selection. We handled the disparity in mortality by a competing risk approach and examined interactions among age group, sex, and procedure. Secondary analysis, including further adjustment for ASA and BMI, was also undertaken. Although matched study designs have been performed in registry studies, there is controversy as to the best study design, and not all confounding variables have been used in matched studies[68]. Other data on patient-related factors, such as dementia, preoperative functional status, and living situation, were not collected. These will clearly influence surgical decisions and outcomes in a way that could not be adjusted for, although they may correlate with ASA scores. We compared only aseptic causes of revision, as infections around HAs may have been treated without component exchange, or with excisional arthroplasty at a higher rate than infections at the site of THAs, which would not have been recorded in the AOANJRR. Patients who might benefit from a revision procedure but are not sufficiently healthy or are unwilling to have a revision conceal some cases of

failure from the AOANJRR database, particularly in the elderly and comorbid patient population. Patient-reported and functional outcome data are not collected by the AOANJRR and were not compared in this study. THA produces higher patient-reported outcome measures and lower pain at longer follow-up compared with HA[15,20,27,69]. This may influence a surgeon's arthroplasty decision and potentially the surgical approach[70]. Functional and quality-of-life outcome differences for FNF treatment are associated with age[29] and are more pronounced in patients who are 60 to 75 years old[28]. RCTs have not identified significant functional differences between patients treated with THA versus HA within 2 to 4 years[1]. Both unipolar and bipolar HA procedures were included since the use of both prosthesis types is common in Australia, and there is controversy as to differences in outcomes[71]. Conducted studies have also not limited inclusion to cemented femoral stems as our study did[72]. Many Australian hospitals also do not allow for a decision option for HA[72], on the basis of the increased cost of bipolar HA and the short life expectancy of many patients selected for HA[71]. Finally, we did not include details on the surgeon performing the procedure, which may be relevant[73,74].

Conclusions

When managing FNF using contemporary surgical options, there was a benefit in revision outcomes for THA in women who were <75 years old and a benefit for HA in women from 80 to 85 years old and in men who were ≥75 years old. There was no difference in revision rates for dislocation between THA and HA. A practical recommendation from this study would be to offer THA for women who are <75 years old. For women from 75 to 80 years old and men from 60 to 75 years old, a decision on THA versus HA is to be made on the basis of life expectancy, with THA to be considered only if the life expectancy is ≥5 years and, on the basis of previous literature and scoring systems, patients are functionally independent and without dementia. HA should be the prosthesis of choice for older patients, those with a shorter life expectancy, or patients without functional independence or with dementia. Future research should more specifically identify validated and objective scoring systems to predict a patient's long-term mortality risk, such that decision-making can be improved to minimize revision procedures.

Appendix

eA Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJS/H139). ■

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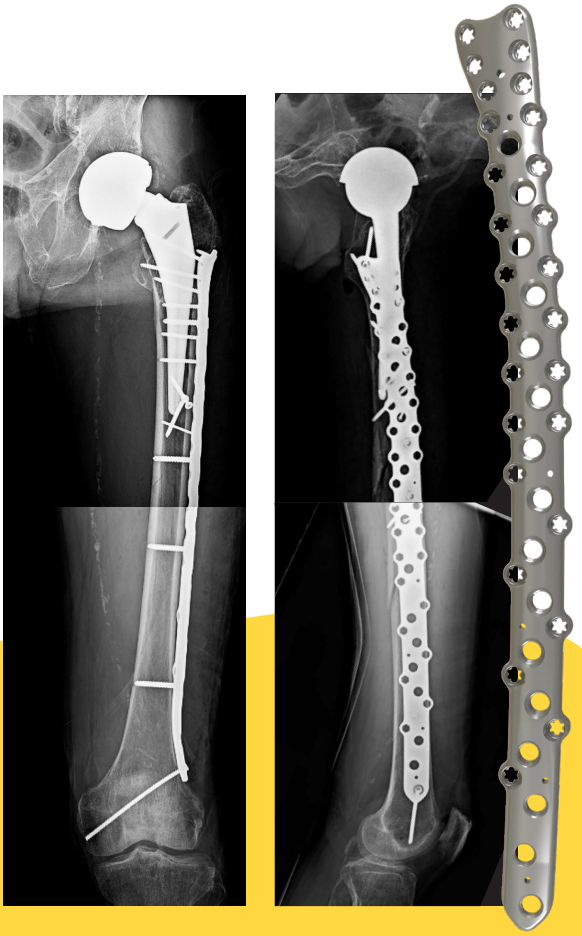

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