Total Hip Arthroplasty Leads to Better Results After Low-Energy Displaced Femoral Neck Fracture in Patients Aged 55 to 70 Years

A Randomized Controlled Multicenter Trial Comparing Internal Fixation and Total Hip Arthroplasty

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Background: The optimal treatment of displaced femoral neck fractures in patients 55 to 70 years old remains controversial. The aim of the present study was to assess the effect of closed reduction and internal fixation with cannulated screws (IF) compared with total hip arthroplasty (THA) on hip pain and function, with use of data for outcome measures, complications, and reoperations.

Methods: This multicenter randomized controlled trial included all patients 55 to 70 years old who presented with a low-energy displaced femoral neck fracture between December 2013 and December 2018. Patients were randomly allocated to undergo either IF or THA. The primary outcome was the Harris Hip Score (HHS) at 12 months postoperatively. Secondary outcomes were the HHS at 4 and 24 months postoperatively, Oxford Hip Score (OHS), Hip Disability and Osteoarthritis Outcome Score (HOOS), health-related quality of life (EQ-5D-3L [EuroQol 5 Dimensions 3 Levels] index score and EQ-VAS [visual analogue scale]), VAS for pain, and VAS for patient satisfaction at 4, 12, and 24 months postoperatively. Complications and reoperations were continuously monitored. The primary analyses were performed according to the intention-to-treat principle.

Results: A total of 102 patients with a mean (± standard deviation) age of 63.7 ± 4.2 years were allocated to IF (n = 51) or THA (n = 51). The mean difference in the primary outcome, the HHS at 12 months postoperatively (5.3; 95% confidence interval, 0.9 to 9.7; p = 0.017), was below the predefined minimal clinically important difference of 10 points. However, patients who underwent THA had a significantly higher HHS at 4 and 12 months, better OHS at 4 and 12 months, and better HOOS at 4, 12, and 24 months postoperatively. Patients who underwent THA also reported better health-related quality of life at 4 months postoperatively and reported greater satisfaction and less pain at 4 and 12 months postoperatively. A total of 26 patients in the IF group (51%; 95% confidence interval, 37% to 65%) and 2 patients in the THA group (4%; 95% confidence interval, 0.5% to 13%) underwent a major reoperation.

Conclusions: In this randomized controlled trial, we showed that patients between 55 and 70 years old who underwent THA for a low-energy displaced femoral neck fracture experienced better outcomes than those who underwent closed reduction and internal fixation.

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

Currently, there is little consensus regarding the optimal treatment of displaced femoral neck fractures in patients between the ages of 55 and 70 years, but a high risk of surgical complications, reduced function, persisting hip pain, and reduced health-related quality of life following the surgical treatment of a hip fracture have been reported in this population[1-3].

Disclosure: The **Disclosure of Potential Conflicts of Interest** forms are provided with the online version of the article (http://links.lww.com/JBJS/H81).

A **Data Sharing statement** is provided with the online version of the article (http://links.lww.com/JBJS/H82).

In elderly patients, arthroplasty is often the treatment of choice because of a lower rate of complications and better functional outcomes compared with closed reduction and internal fixation (IF) with cannulated screws[4-9].

Most femoral neck fractures in middle-aged patients occur as a result of low-energy trauma, and these patients are often biologically aged and have symptomatic comorbidities[3,10-12]. IF has been recommended for patients <60 years old[1,13-15]. However, the risk of reoperation for mechanical failure, nonunion, or osteonecrosis is high following IF[1,16-18]. Furthermore, the risk of complications is even greater in hips converted to total hip arthroplasty (THA) following failed IF, and hip function and quality of life might be inferior compared with primary THA[19].

Therefore, we conducted an interventional multicenter randomized controlled trial (RCT) comparing IF performed with use of cannulated screws and THA for the treatment of displaced femoral neck fractures in patients 55 to 70 years old. We hypothesized that patients undergoing THA would experience superior results compared with those undergoing IF, according to hip function, mobility, and pain; health-related quality of life; patient satisfaction; and reoperations. The primary outcome was the Harris Hip Score (HHS) at 12 months.

Materials and Methods

Study Design and Participants

This RCT was conducted at 2 Norwegian level-III trauma hospitals. Patients were examined and completed trial outcome measures at the time of admission, postoperatively before discharge, and at 4, 12, and 24 months postoperatively. Complications were monitored continuously. Patients were included who were admitted to either of the 2 trial centers, resided within the hospital catchment areas, and were cognitively able (Fig. 1). Patients were excluded who had a femoral neck fracture older than 7 days, concomitant pelvic or lower-extremity fracture, an expected life span of <12 months as judged by the surgeon, an American Society of Anesthesiologists[20] (ASA) grade of 4 or 5, an amputated lower extremity, neuromuscular diseases possibly affecting treatment with THA, any drug abuse, or pathological hip fracture. From December 2013 to December 2018, we enrolled a total of 102 patients 55

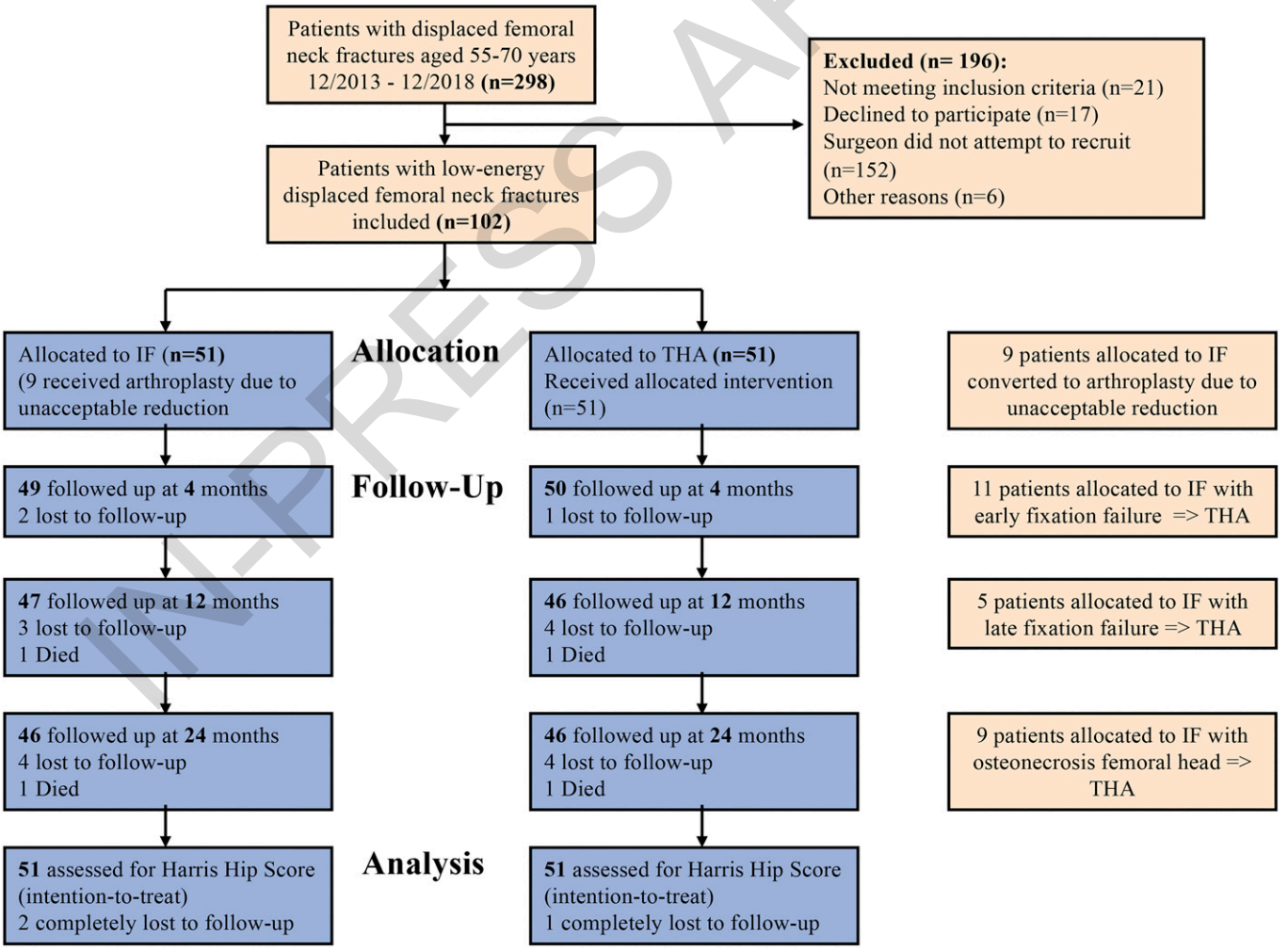

Fig. 1
CONSORT (Consolidated Standards of Reporting Trials) flow diagram.

to 70 years old with a displaced femoral neck fracture. Patients were randomly allocated to undergo either IF (n = 51) or THA (n = 51) (Fig. 1).

The surgeon on call classified fractures as either nondisplaced or displaced according to the simplified Garden classification[21]. In addition, Garden-I or II femoral neck fractures with a posterior tilt of ≥20° were classified as displaced[22,23]. The anesthesiologist on call classified the ASA grade of the patient. All patients received written and oral information before signing informed consent.

Interventions

Patients were prioritized for surgery no later than 48 hours after admission. IF was performed via closed reduction with use of biplanar fluoroscopy with the patient on a traction table. Anatomical reduction was sought by reducing any varus malalignment and/or substantial posterior tilt[22,23]. Some degree of shortening of the femoral neck was accepted. Fracture fixation was performed with use of 2 parallel cannulated screws, which is the most commonly utilized method in Scandinavia[24-26]. If closed reduction was unacceptable, a consultant with ≥6 years of experience in hip-fracture treatment attempted 1 additional closed reduction maneuver. If still not acceptable, the procedure was converted to arthroplasty during the same anesthesia session.

THAs were performed with use of the latest-generation, modular implants, which were typically cemented. Antibiotic-loaded bone cement was utilized. A prosthetic head size of 32 mm or dual-mobility cup was utilized. The hip implant and surgical approach to the hip joint were in line with the established standard treatment at the trial centers. All patients received perioperative intravenous antibiotics and postoperative antithrombotic prophylaxis (5,000 IU low-molecular-weight heparin once daily for 2 weeks). Early mobilization and full weight-bearing were encouraged in both trial arms.

Outcomes

The primary outcome was the HHS at 12 months[27]. Secondary outcomes were the HHS at 4 and 24 months, Oxford Hip Score

TABLE I Primary and Secondary Outcome Measures

Outcome Measure	Description of Measure	Score Interpretation	MCID or MDC*	Assessment Time Points	Assessor Blinding
HHS	Hip function (0-47 points), pain (0-44 points), range of motion (0-5 points), and deformity (0-4 points)	<70 = poor, 70-79 = fair, 80-89 = good, 90-100 = excellent	MCID 10	Prefracture and 4, 12, and 24 months	Surgeon and investigator unblinded
OHS	Hip function (0-48 points)	<27 = poor, 27-33 = fair, 34-41 = good, >41 = excellent	MCID 5.2	Prefracture and 4, 12, and 24 months	Surgeon and investigator unblinded
HOOS	5 subscales, measuring pain, symptoms, function in activity of daily living, function in sport and recreation, and quality of life, scored from 0 = worst to 100 = best	Each subscale is scored separately: <70 = poor, 70-79 = fair, 80-89 = good, 90-100 = excellent	MDC pain: 21.6, symptoms: 22.7, activities of daily living: 17.7, quality of life: 24.4	Prefracture and 4, 12, and 24 months	Surgeon and investigator unblinded
EQ-5D-3L	Quality of life, patient-reported, in 5 dimensions: mobility, self-care, usual activity, pain/discomfort, anxiety/depression; each dimension with 3 levels: no problems, some problems, and extreme problems	<0 = worse than death, 0 = death, 1 = highest quality of life	MCID 0.1	Postop. At discharge and 4, 12, and 24 months	Surgeon and investigator unblinded
EQ-VAS	Health related quality of life, patient-reported, Visual analogue scale, range 0-100	0 = worst imaginable health, 100 = best imaginable health	MCID 7	Postop. and 4, 12, and 24 months	Surgeon and investigator unblinded
VAS pain	Pain, patient-reported, range 0-100	0 = no pain, 100 = worst imaginable pain	MCID 10	Postop. and 4, 12, and 24 months	Surgeon and investigator unblinded
VAS patient satisfaction	Satisfaction, patient-reported, range 0-100	0 = maximally satisfied, 100 = maximally dissatisfied	MCID 10	Postop. and 4, 12, and 24 months	Surgeon and investigator unblinded

*MCID and MDC were predefined according to published data and clinical practice[30-35].

TABLE II Patient Characteristics at Baseline*

	IF (N = 51)	THA (N = 51)	Total (N = 102)
Age *(yr)*	64.1 ± 4.3	63.4 ± 4.0	63.7 ± 4.2
Sex by age group, F/M			
55-59 years	6 (16.2)/2 (14.3)	6 (18.8)/6 (31.6)	12 (17.4)/8 (24.2)
60-64 years	12 (32.4)/2 (14.3)	10 (31.3)/6 (31.6)	22 (31.9)/8 (24.2)
65-70 years	19 (51.4)/10 (71.4)	16 (50.0)/7 (36.8)	35 (50.7)/17 (51.5)
Female	37 (72.5)	32 (62.7)	69 (67.6)
BMI *(kg/m²)*	24.7 ± 4.6	25.2 ± 3.9	24.9 ± 4.3
ASA classification			
1	7 (13.7)	4 (7.8)	11 (10.8)
2	30 (58.8)	38 (74.5)	68 (66.7)
3	14 (27.5)	9 (17.6)	23 (22.5)
Charlson comorbidity index score	2.8 ± 1.0	2.5 ± 1.1	2.7 ± 1.0
mMRC Dyspnea scale			
0	34 (66.7)	36 (70.6)	70 (68.6)
1	14 (27.5)	14 (27.5)	28 (27.5)
2	3 (5.9)	1 (2.0)	4 (3.9)
NYHA			
0	10 (19.6)	8 (15.7)	18 (17.6)
1	38 (74.5)	39 (76.5)	77 (75.5)
2	3 (5.9)	3 (5.9)	6 (5.9)
3	0	1 (2.0)	1 (1.0)
Current smokers	26 (51.0)	19 (37.3)	45 (44.1)
Alcohol abuse	7 (13.7)	8 (15.7)	15 (14.7)
Residence			
Living at home	49 (96.1)	50 (98.0)	99 (97.1)
With public assistance	1 (2.0)	1 (2.0)	2 (2.0)
Institution	1 (2.0)	0	1 (1.0)
Civil status			
Unmarried	7 (13.7)	13 (25.5)	20 (19.6)
Married	34 (66.7)	32 (62.7)	66 (64.7)
Widowed	8 (15.7)	5 (9.8)	13 (12.7)
Divorced	2 (3.9)	1 (2.0)	3 (2.9)
Established osteoporosis	10 (19.6)	6 (11.8)	16 (15.7)
Fall from standing height			
Indoors	28 (54.9)	22 (43.1)	50 (49.0)
Outdoors	23 (45.1)	29 (56.9)	52 (51.0)
Died during follow-up	1 (2.0)	1 (2.0)	2 (2.0)

*Values given as the mean ± SD or as the count with the percentage in parentheses. BMI = body mass index, mMRC = Modified British Medical Research Council, and NYHA = New York Heart Association.

(OHS), and Hip Disability and Osteoarthritis Outcome Score (HOOS) at 4, 12, and 24 months after surgery[28,29]. Minimal clinically important differences (MCIDs) and minimal detectable changes (MDCs) were defined according to clinical practice and previously published data (Table I)[30-35]. The 1-week prefracture levels for the HHS, OHS, and HOOS were assessed at the time of admission. Patients completed the EQ-5D-3L (EuroQol 5 Dimensions 3 Levels) and EQ-VAS (visual analogue scale), VAS for pain, and VAS for patient satisfaction postoperatively before discharge. Comorbidity was reported with use of ASA classification, Charlson comorbidity index score, New York Heart Association, and Modified British

TABLE III Hip Implants Utilized

IF (N = 51)	THA (N = 51)
• 36 patients: hip pins (8-mm cannulated, partially threaded) (Smith&Nephew) • 6 patients: Olmed hip pins (8-mm cannulated partially threaded) (DePuy Synthes) • 9 patients: converted to arthroplasty during index procedure	• 29 patients: Exeter/X3 RimFit (Stryker) • 10 patients: Lubinus SP II/IP (LINK) • 4 patients: CPT/Müller (Zimmer Biomet) • 3 patients: Corail/Marathon (DePuy Synthes) • 2 patients: Exeter (Stryker)/Avantage* (Zimmer Biomet) • 2 patients: Lubinus SP II (LINK)/Polar* (Smith&Nephew) • 1 patient: CPT/Avantage* (Zimmer Biomet)

*Dual-mobility prosthesis with 28-mm femoral head size.

Medical Research Council Dyspnea scale[36-38]. VAS pain and patient satisfaction and validated Norwegian versions of the EQ-5D-3L and the EQ-VAS were assessed during the hospital stay and at the time of each follow-up. VAS pain and patient satisfaction were measured on a 100-point scale, with 0 indicating favorable results (i.e., no pain and the highest possible satisfaction, respectively) and 100 indicating unfavorable results (i.e., unbearable pain and the lowest possible satisfaction). The EQ-VAS was measured on a 20-cm, 100-point scale, with 0 indicating the worst possible health and 100 indicating the best possible health[39]. We utilized the EQ-5D-3L index scores proposed by a British study[40]. Reoperations and complications were recorded continuously. Reoperations were designated as either major or minor. Minor reoperations were defined as a closed reduction of a dislocated THA or the removal of screws only.

Sample Size

We assumed a difference of 10 HHS points between the treatment groups as a clinically relevant difference. To detect a difference of 10 HHS points between IF and THA with significance set at 0.05, 80% power, and an assumed standard deviation (SD) of 15 points in each group, a total of 36 patients were needed in each group. We expected that 15% to 20% of patients in each group would discontinue study participation. When secondary

TABLE IV Surgical Details*

	IF (N = 51)	THA (N = 51)	P Value
Type of fixation			
Screw fixation	42		
Conversion to cemented THA during index surgery	9		
Fixation of prosthesis			
Cemented		48 (94.1)	
Reverse hybrid		3 (5.9)	
Duration of surgery *(min)*	43.3 ± 28.5	107.4 ± 22.9	<0.001†
Surgeon experience of >3 years	45 (88.2)	49 (96.1)	0.020‡
Hip joint approach			
Direct lateral		34 (66.7)	
Posterior		17 (33.3)	
Intraoperative blood loss§ *(mL)*	119.6 ± 144.4	418.8 ± 208.1	<0.001†
Need for blood transfusion	2 (3.9)#	4 (7.8)	
Postoperative complication			
Urinary tract infection**	7 (13.7)	2 (3.9)	
Pneumonia	0	2 (3.9)	
Deep vein thrombosis**	1	0	
Pulmonary embolism**	1	0	
Alcohol abstinence	0	1 (2.0)	

*Values are given as the mean ± SD or as the count with or without the percentage in parentheses †Independent-samples t test ‡Chi-square test §Intraoperative blood loss data were missing for 14 patients in the IF group and 2 patients in the THA group #Both of these were patients who underwent intraoperative conversion to THA **One patient had 3 different postoperative complications.

TABLE V Outcomes

Outcome	IF (N = 51)		THA (N = 51)		IF Versus THA*	
	N	Mean ± SD	N	Mean ± SD	Mean Diff. (95% CI)	P Value
HHS						
Prefracture	51	93.0 ± 10.3	51	96.0 ± 7.2	−3.0 (−7.2 to 1.2)	0.158
4 months	49	74.5 ± 16.4	50	86.1 ± 10.1	−11.6 (−15.9 to −7.4)	<0.001†
12 months	47	84.5 ± 11.6	46	89.8 ± 10.2	−5.3 (−9.7 to −0.9)	0.017†
24 months	46	87.9 ± 10.6	46	92.3 ± 8.6	−4.2 (−8.6 to 0.2)	0.062
OHS						
Prefracture	51	45.3 ± 5.5	51	46.1 ± 3.9	−0.9 (−3.5 to 1.8)	0.522
4 months	49	32.7 ± 11.2	50	40.2 ± 6.8	−7.5 (−10.2 to −4.8)	<0.001†
12 months	47	39.0 ± 7.8	46	43.4 ± 6.2	−4.3 (−7.1 to −1.6)	0.002†
24 months	46	41.6 ± 6.5	46	44.1 ± 4.8	−2.4 (−5.2 to 0.3)	0.081
HOOS pain						
Prefracture	51	92.8 ± 13.2	51	94.5 ± 12.1	−1.7 (−7.7 to 4.4)	0.595
4 months	49	68.3 ± 22.1	50	86.5 ± 13.4	−18.1 (−24.3 to −11.9)	<0.001†
12 months	47	74.8 ± 20.7	46	90.4 ± 12.1	−15.7 (−22.0 to −9.4)	<0.001†
24 months	46	79.7 ± 18.4	46	91.6 ± 10.6	−11.7 (−18.1 to −5.4)	<0.001†
HOOS symptoms						
Prefracture	51	92.0 ± 15.0	51	96.2 ± 7.9	−4.2 (−10.6 to 2.1)	0.190
4 months	49	60.5 ± 24.3	50	83.4 ± 13.2	−22.9 (−29.3 to −16.4)	<0.001†
12 months	47	74.9 ± 19.2	46	86.5 ± 17.0	−11.4 (−18.0 to −4.8)	0.001†
24 months	46	79.1 ± 17.0	46	88.2 ± 14.1	−8.6 (−15.2 to −2.0)	0.011†
HOOS activities of daily living						
Prefracture	51	91.9 ± 18.4	51	95.7 ± 8.8	−3.8 (−10.0 to 2.4)	0.229
4 months	49	66.4 ± 23.0	50	84.4 ± 12.1	−18.0 (−24.2 to −11.7)	<0.001†
12 months	47	77.1 ± 19.0	46	89.1 ± 13.3	−12.0 (−18.4 to −5.6)	<0.001†
24 months	46	79.8 ± 18.2	46	91.1 ± 10.8	−11.1 (−17.5 to −4.6)	0.001†
HOOS sport						
Prefracture	51	88.6 ± 23.1	51	89.4 ± 21.0	−0.8 (−9.6 to 8.1)	0.862
4 months	49	48.1 ± 25.7	50	67.9 ± 21.3	−19.7 (−28.6 to −10.7)	<0.001†
12 months	47	65.0 ± 23.8	46	77.0 ± 22.0	−12.5 (−21.7 to −3.4)	0.007†
24 months	46	65.6 ± 25.9	46	79.1 ± 21.9	−13.6 (−22.8 to −4.4)	0.004†
HOOS quality of life						
Prefracture	51	91.7 ± 17.5	51	94.1 ± 14.6	−2.4 (−15.6 to 10.9)	0.726
4 months	49	49.2 ± 26.0	50	77.4 ± 18.3	−28.2 (−41.7 to −14.7)	<0.001†
12 months	47	61.6 ± 22.5	46	94.2 ± 83.2	−32.6 (−46.5 to −18.7)	<0.001†
24 months	46	66.4 ± 23.3	46	83.6 ± 19.4	−17.1 (−31.0 to −3.1)	0.017†
EQ-5D-3L index score						
Postoperative	50	0.52 ± 0.35	49	0.59 ± 0.37	−0.07 (−0.17 to 0.04)	0.195
4 months	48	0.61 ± 0.34	48	0.86 ± 0.17	−0.24 (−0.35 to −0.13)	<0.001†
12 months	45	0.79 ± 0.25	43	0.91 ± 0.12	−0.08 (−0.16 to 0.03)	0.157
24 months	46	0.81 ± 0.25	46	0.9 ± 0.12	−0.02 (−0.15 to 0.11)	0.756
EQ-VAS						
Postoperative	48	59.5 ± 16.2	50	60.3 ± 20.3	−2.7 (−9.8 to 4.4)	0.454
4 months	49	63.0 ± 16.9	49	70.3 ± 20.2	−4.5 (−10.5 to 1.4)	0.132
12 months	47	69.3 ± 20.0	44	75.8 ± 18.4	−7.6 (−14.9 to −0.4)	0.040†
24 months	46	64.1 ± 22.4	46	76.3 ± 19.0	−10.9 (−18.7 to −3.1)	0.006†

continued

TABLE V (*continued*)

Outcome	IF (N = 51)		THA (N = 51)		IF Versus THA*	
	N	Mean ± SD	N	Mean ± SD	Mean Diff. (95% CI)	P Value
VAS pain						
Postoperative	48	41.0 ± 21.8	50	33.0 ± 24.7	5.7 (−1.4 to 12.8)	0.118
4 months	49	36.7 ± 26.9	50	10.5 ± 13.9	23.9 (16.6 to 31.1)	<0.001†
12 months	47	20.8 ± 21.7	45	8.4 ± 14.0	9.3 (1.8 to 16.8)	0.015†
24 months	46	15.8 ± 15.6	46	7.9 ± 11.0	4.0 (−3.5 to 11.5)	0.296
VAS satisfaction						
Postoperative	41	21.2 ± 23.5	42	15.0 ± 16.9	6.4 (0.0 to 12.8)	0.050
4 months	49	25.9 ± 25.1	50	10.1 ± 16.8	10.6 (5.9 to 15.3)	<0.001†
12 months	47	20.1 ± 22.2	45	9.9 ± 17.0	13.3 (6.7 to 20.0)	<0.001†
24 months	46	19.0 ± 26.7	46	10.2 ± 15.4	3.3 (−4.1 to 10.6)	0.382

*Results of linear mixed model. †Significant.

end points, complications, and reoperations were considered, and with the assumption that about a 30% complication rate would be found in the IF group and only a 10% complication rate in the THA group, we aimed to include 59 patients in each group. We had, however, lower loss to follow-up than estimated, hence retaining the statistical power with lower recruitment. In addition, the inclusion period was longer than expected and we experienced an increasing reluctance from patients to consent, especially because of a preference for THA. Thus, we decided to stop inclusion after allocation of 51 patients to each trial arm.

Randomization

Block randomization to either IF or THA was performed, with block sizes between 4 and 10. After inclusion, the surgeon on call randomized the eligible patients with use of numbered, sealed, and opaque envelopes. The envelopes were prepared by personnel who had no other role in the trial. Neither surgeons nor patients were blinded to treatment.

Statistical Analysis

Patient baseline characteristics were presented as means and SDs or as frequencies and percentages. Surgical details were compared between groups with use of an independent-samples t test or chi-square test, as appropriate. The HHS, OHS, HOOS, EQ-5D-3L index score, EQ-VAS, VAS pain, and VAS satisfaction were presented as means and SDs. For the primary analysis, the independent-samples t test was utilized to assess the difference between groups in the HHS score at 12 months. Linear mixed models with fixed effects for a third-order time polynomial, group (i.e., IF versus THA), and the interaction between these were estimated to assess differences between groups in the HHS, OHS, HOOS, EQ-5D-3L index score, EQ-VAS, VAS pain, and VAS satisfaction at all time points. Random effects for patients were included in the linear mixed-model analysis to account for within-patient correlations as a result of repeated measurements. The possible clustering effect at the trial center level was assessed by intraclass correlation coefficients and was negligible. A significant interaction would imply that there could be a difference between the groups regarding the trend in the outcome variable. The results were illustrated graphically by plotting the estimated means with the corresponding 95% confidence intervals (CIs). As post hoc analyses, mean differences between the groups at each time point were derived together with 95% CIs and p values. Nine patients randomized to IF were converted to THA. These patients remained in the IF group according to the intention-to-treat principle. All tests were 2-sided, and significance was set at 0.05. All analyses were performed in SPSS (version 27; IBM) and SAS (version 9.4; SAS Institute).

Source of Funding

The study was conducted by Akershus University Hospital, Lørenskog, Norway and Haukeland University Hospital, Bergen, Norway. No external funding was received for this study.

Results

The study was approved by the Regional Committee for Ethics in Medical Research Southeast Norway (REK-ref.:2013/1023) and was registered at ClinicalTrials.gov (NCT02085707).

Demographics

The mean age of the trial population was 63.7 ± 4.2 years, and 68% were women (Table II). A larger proportion of patients in the IF group were current smokers and diagnosed with osteoporosis compared with those in the THA group (Table II). Three patients were lost to follow-up, and 1 patient in each group died during the follow-up period (Fig. 1).

Surgical Details

Data related to implants and surgical approaches are presented in Tables III and IV, respectively. Operative time was longer and intraoperative blood loss was higher in the THA group. More patients in the THA group were treated by experienced

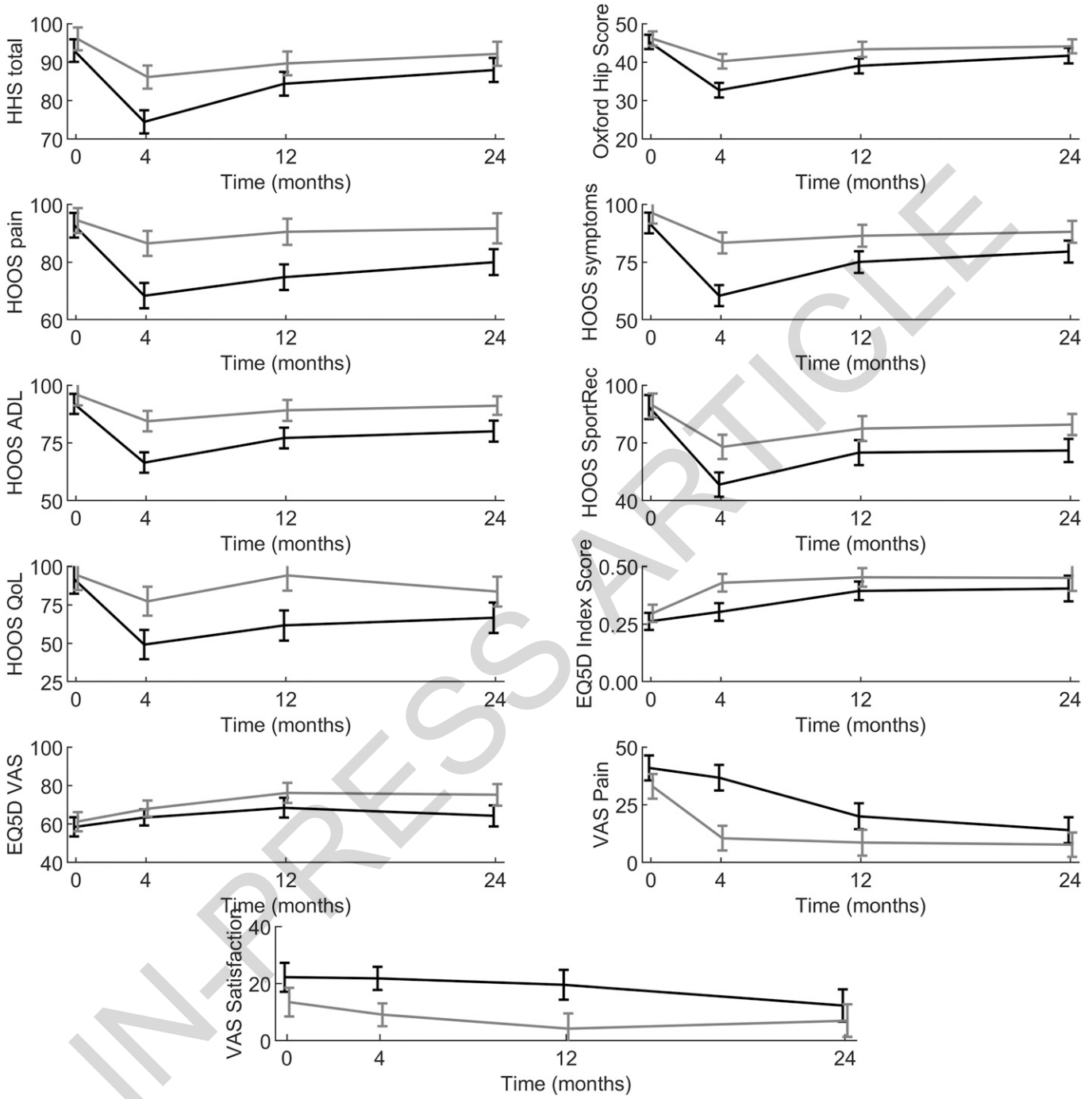

Fig. 2

Graphs showing HHS, OHS, HOOS, EQ-5D-3L index score, EQ-VAS, VAS pain, and VAS patient satisfaction at 4, 12, and 24 months. Presented as means and 95% CIs. Black line = IF, gray line = THA, ADL = activities of daily living, and QoL = quality of life.

surgeons. There were no differences in the rates of postoperative complications between groups (Table IV).

Outcome Measures

The HHS at 12 months postoperatively was superior in the THA group (89.8 ± 10.2 points) compared with the IF group (84.5 ± 11.6) (Table V). Although significant, the mean difference of 5.3 points (95% CI, 0.9 to 9.7; p = 0.017) was smaller than the predefined MCID. Overall, the THA group had better results than the IF group for all secondary outcome measures (Fig. 2, Table V), including significantly better scores in all dimensions of the HOOS at all postoperative time points;

significantly better HHS, OHS, VAS pain, and VAS patient satisfaction at 4 and 12 months; significantly better EQ-5D-3L index score at 4 months; and significantly better EQ-VAS at 12 and 24 months (Table V).

Reoperations

A total of 9 patients (18%) allocated to the IF group underwent conversion to arthroplasty at the time of the index surgical procedure because of unacceptable fracture reduction (Table VI). Reoperations were performed in 34 patients in the IF group (67%; 95% CI, 52% to 79%) and 2 patients in the THA group (4%; 95% CI, 0.5% to 13%) (Table VI). Of these, 26 patients in the IF group (51%; 95% CI, 37% to 65%) underwent a major reoperation, including 25 who underwent a secondary THA and 1 who underwent a Girdlestone procedure (resection arthroplasty) for a deep infection. Both of the patients in the THA group who required a secondary procedure underwent a major reoperation, including 1 exchange of the acetabular components for malalignment and 1 removal of leaking bone cement. There were no dislocations in the THA group.

TABLE VI Reoperations and Interventions*

	IF (N = 51)	THA (N = 51)	P Value†
IF converted during index procedure	9		
To THA	8		
To hemiarthroplasty	1		
Reoperation	34 (66.7)	2 (3.9)	<0.001†
Major reoperation	26 (51.0)	2 (3.9)	<0.001†
Early fixation failure§ (<4 month)	11		
Late fixation failure§ (≥4 month)	5		
Osteonecrosis§	9		
Deep infection	1		
Cement leak		1	
Acetabular cup misplacement		1	
Dislocation of prosthesis		0	
Minor reoperation#	8 (15.7)		

*Values are given as the count with or without the percentage in parentheses. †Chi-square test. †Significant §Converted to THA. #Removal of screws only.

Discussion

In this RCT, THA led to superior hip function, as assessed with use of the HHS at 12 months postoperatively; however, the mean difference between the THA and IF groups was below the predefined MCID of 10 points. Most secondary outcomes were superior in the THA group as well, with mean differences higher than their respective MCIDs, especially at 4 months postoperatively.

A total of 43 patients (84%) in the IF group underwent either conversion to THA during the index procedure (9 patients; 18%) or a subsequent reoperation during the 24-month follow-up period (34 patients; 67%), which represents a greater proportion than has been reported in previous studies[1,16,18,41-43]. When interpreting the results of the present study—particularly the primary outcome, the HHS at 12 months postoperatively—it is important to consider the relatively large number of patients in the IF group who underwent early conversion to arthroplasty. These patients, who likely had relatively poorer functional and patient-reported outcomes before the reoperation, would not have completed the questionnaire at that time point. As such, the intention-to-treat-analysis likely overestimated the effects of treatment with IF. This may explain both the small difference in the HHS between the treatment groups at 12 months postoperatively and the improvement in the HHS from 4 to 12 months postoperatively observed in the IF group. Similar patient-reported outcomes at 1 year were reported in a previous Swedish cohort[44]. Additionally, it may be necessary to consider both the individual and socioeconomic burdens of the high number of reoperations in patients allocated to the IF group[45]. For these reasons, we chose to rely heavily on the secondary outcome measures when deriving conclusions in the present study.

We believe that this trial was sufficiently powered and that our findings are robust and representative; however, there were certain limitations. Patient inclusion took longer than expected, and this trial could be underpowered for some of the secondary outcomes. Outcome thresholds or specific criteria for reoperations were not predefined in the study protocol. We believe that the decision regarding a reoperation must be made jointly by the surgeon and patient, weighting subjective views of the clinical situation, which precludes the use of any strict criteria. Lack of such predefined revision criteria could potentially lower the threshold for reoperation after IF as opposed to THA. Furthermore, the sample size was too small to accurately assess the need for reoperations. Specific differences in baseline characteristics could imply an imbalance between the groups. The majority of patients included were within the oldest age category, and the mean age was 64 years. This may mean that our findings were most valid for patients ≥60 years old. The large number of smokers and patients with established osteoporosis may also have led to an increased risk of reoperation. However, the high rate of conversions to THA during the index procedure and early fixation failures and could not be explained by smoking status and osteoporosis. Additionally, for IF, we did not attempt to perform open reduction and utilized 2 rather than 3 screws, which is consistent with Scandinavian practices. The configuration and the numbers of screws utilized in this trial could have affected the high rate of reoperations following IF. The stability of 2-screw fixation has been questioned, but there is little evidence to support that the risk of fixation failure is reduced by adding 1 additional screw[46]. Surgeon experience and the quality of reduction might affect fracture healing, fixation failure, and the risk of osteonecrosis[1,47,48].

The 2-year follow-up may have been too short to detect late complications, particularly for THA; however, studies with

long-term follow-up often identify few or no late revisions of primary THA[41,43]. In particular, the use of a cemented femoral stem has been associated with lower long-term revision rates[7,16,26,43,44,49]. A longer follow-up could naturally also highlight the risk of revision arthroplasty in patients who undergo primary IF. In Scandinavia, the preferred treatment for healthy "young old" patients shifted from IF to THA during the last 2 decades[16,26]. In contrast with Anglo-Saxon countries, surgeons in Scandinavian countries do not often consider the use of hemiarthroplasty in this patient group[50,51].

To summarize, this multicenter study showed that THA led to superior hip function and less hip pain compared with IF in patients 55 to 70 years old with a low-energy displaced femoral neck fracture. Although the mean difference between trial groups for the HHS at 12 months was below the predetermined MCID, most secondary outcomes were superior in the THA group. Patients allocated to the IF group had a higher risk of reoperation than those allocated to the THA group. Future trials comparing IF and THA in patients around the retirement age should include large cohorts and focus on long-term results.

In conclusion, this open-label RCT of patients 55 to 70 years old with low-energy displaced femoral neck fractures showed that THA was superior to IF. ■

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