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Function, sarcopenia and osteoporosis 10 years after a femoral neck fracture in patients younger than 70 years

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ABSTRACT

Background and purpose: A femoral neck fracture (FNF) may have long-term effects on the patient's function, also in patients younger than 70 years. These long-term effects are not well described, since most studies have short follow-ups. The aim of this study was to investigate clinical outcome by performance-based functional tests, hand grip strength, and hip function in different subgroups. The secondary aim was to study surgical complications, bone mineral density (BMD) and occurrence of sarcopenia 10 years after a FNF.

Patients and methods: A prospective multicenter study with a 10-year follow-up of patients aged 20–69 years with a FNF treated with internal fixation (IF). Five-times sit-to-stand test (5TSST), 4-m walking speed test, hand grip strength (HGS) and Harris Hip Score (HHS) were performed.

A radiographic examination of the hip was performed and re-operations were registered. Bone mineral density (BMD) at the hip, spine and total body composition were assessed with dual energy x-ray absorptiometry (DXA). Present sarcopenia was determined by the combination of reduced functional performance and low fat-free mass index (FFMI).

Results: A total of 58 patients were included. 5TSTS was normal in 45% of the patients and old age was associated with poorer performance ($p<0.001$). 76% of the study population had a normal speed gait and likewise, old age ($p = 0.005$) and walking aids ($p = 0.001$) were associated with poor performance. HGS was normal in 82% of the men and 64% of the women. HHS showed that 85% had a good/excellent function. A major re-operation was performed in 34% of the patients with displaced FNF and in 20% of patients with non-displaced FNF. 74% displayed osteopenia and 12% osteoporosis. 17% of the men and 38% of the women had sarcopenia.

Interpretation: The majority of patients less than 70 years of age with a FNF treated with IF, had normal functional tests, muscle strength and a good hip function ten years post-operatively. However, one in ten had osteoporosis, and one third was sarcopenic which indicate the importance of encouraging regular muscle preserving resistance training after hip fracture.

Introduction

Femoral neck fractures (FNF) are uncommon in patients younger than 70 years of age, but may result in lifetime disability [1,2]. Surgical or general postoperative complications have traditionally been used to evaluate the clinical results after a hip frac-

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ture [1,3]. However, to evaluate patientś function post-operatively might be even more relevant, especially for younger patients [4].

Studies on patients with a hip fracture with a follow-up exceeding two years are mainly register-based, retrospective and usually includes elderly populations [5,6]. Main focus is often surgical failures, while functional outcomes are usually not noticed [1,3,7].

Many elderly patients as well as patients less than 70 years of age at the time of fracture have a low bone mineral density (BMD) [8,9] but it is unclear if this further deteriorates the following 10 years after the fracture. The prevalence of sarcopenia, i.e. the combined reduction of muscle strength and muscle mass [10], in hip fracture patients has been reported to be 17–58%, depending on population and definition of sarcopenia [11,12]. However, no studies have examined the frequency of sarcopenia 10 years after a FNF in patients younger than 70 years of age.

The aim of this study was to investigate clinical outcomes by functional performance tests, muscle strength and hip function as well as surgical complications, bone mineral density (BMD) and occurrence of sarcopenia 10 years after a FNF in patients 20–69 years at the time of fracture.

Materials and methods

This is a 10-year follow-up study of a subgroup of patients from an earlier multicenter study in patients aged 20–69 years with a FNF (Garden 1–4) [13]. All patients were admitted to any one of the four university hospitals in Stockholm, Sweden during the years 2003–2005. Patients had an operation with a closed fracture reduction (Garden 3–4) and internal fixation (CRIF) with two cannulated screws. Only patients who were able to walk before the fracture and living independently were included. At the time of fracture, patients with psychotic disease or cognitive impairment according to Short Portable Mental Status Questionnaire (SPMSQ <3) [14] were excluded. Patients with a fracture older than 48 h before admission, previous pathology in the fractured hip, and risk factors for secondary osteoporosis (hyperparathyroidism and chronic renal failure) were also excluded.

For the 10-year follow-up, patients from three of the participating university hospitals were contacted, whereas patients initially from the fourth university hospital were excluded due to lack of resources for a re-examination. Deceased patients were registered.

The following variables were recorded at the 10-year follow-up: age, gender, BMI, re-operations and new fractures since index operation. Moreover, living conditions, walking ability, walking aids or not, smoking and American Society of Anesthesiologists classification (ASA) [15] were recorded. Functional tests were conducted and each test session started with a physical examination of the hip following a standardized protocol including Harris Hip Score (HHS) [16]. Performance-based functions were evaluated by five-times sit-to-stand test (5TSTS) [17], 4-m walking speed test [18] and hand grip strength (HGS) measured by Jamar hand dynamometer [19]. Radiography of the previously fractured hip was taken and re-operations were registered. Extractions of the screws were coded as minor surgery and conversion to a total hip replacement (THR) was coded as a major re-operation. Total body, spine and hip BMD (contralateral side) and body composition were measured by dual energy x-ray absorptiometry (DXA). Presence of sarcopenia was defined by the combination of the low fat-free mass index (FFMI) and a low outcome in any of the functional performance tests and strength in accordance with European Working Group on Sarcopenia in Older People 2 (EWGSOP2) [10].

Muscle strength

HGS (kg) was measured in the dominant hand (JAMAR 50,301 J) with the patients in a sitting position and the highest value of three hand grip attempts was registered. Cut-off points used for low HGS indicating sarcopenia were < 16 kg in women and < 27 kg in men [10]. HGS measured with a hand dynamometer is an easy and recommended way to assess muscle strength [20]. The Jamar hand dynamometer is the most widely used instrument with good reproducibility ($r > 0.80$) and reliability ($r = 0.98$) [20].

Performance based functional tests

5TSTS was conducted by measuring the time taken to stand up from a sitting position five times as fast as possible without the use of the arms [21]. The patients performed the entire test three times with at least 5-minute rest between the tests and the mean result was calculated. Cut-off points for sarcopenia according to EWGSOP2 are >15 s for five rises [10]. 5TSTS is often used in clinical practice [22]. The performance on this test is based upon lower limb strength, especially quadriceps strength, and has been suggested as an alternative measure for lower limb strength in older people [23]. Subjects who need more than 15 s to complete the test have a 74% greater risk of recurrent falls [24].

In the 4-meter walking speed test the patients were instructed to walk their normal pace with their assistive device if necessary. The patients walked down a hallway through a 1-meter zone for acceleration, a central 4-meter “testing” zone and a 1-meter zone for deceleration [25]. The timer started with the first footfall after the 0-meter line and stopped with the first footfall after the 4-meter line. The patients repeated the test three times and the best score was recorded. A cutoff value of less than 0.8 m/*sec* could indicate sarcopenia according to EWGSOP2 [10]. Epidemiological studies of reliability and validity of gait speed assessment in elderly indicate that this parameter is an independent predictor of a wide range of poor clinical outcomes in older persons, including disability, falls, hospitalization/institutionalization and mortality [26,27].

Body composition and definition of sarcopenia

Body composition, total lean body mass (LM), fat mass and bone mineral content (BMC) were also measured. The sum of BMC and LM represents fat-free mass (FFM). To normalize for body size, the fat-free mass index (FFMI, kg/m²) was calculated by dividing the FFM by height squared. Fat mass index (FMI, kg/m²) was calculated analogously [28]. Cut-offs for low FFMI indicating sarcopenia for men were <17 kg/m² and <15 kg/m² for women [29]. Sarcopenia was diagnosed if the patients displayed values below cut-off both for FFMI and for either HGS or 5TSTS in accordance with EWGSOP2 [10].

Hip function

The postoperative hip function was measured by Harris Hip Score (HHS), a validated instrument that evaluates pain, function, range of motion and deformity of the hip [16]. It has a scale of 100 points in which pain constitute 44 points. Severe pain at rest gives a value of 0 and no pain gives a value of 44. Function has a maximum level of 43 points and includes evaluation of walking ability and daily activities. Maximum range of motions gives 5 points and absence of deformities gives 4 points. HHS is categorized as excellent if > 80, good between 70 and 80 and poor at < 70 points [16].

Bone mineral density measurements

BMD was measured by DXA using Hologic (Hologic corp.) or Lunar (Lunar corp.) densitometers. The BMD on the contralateral hip

Table 1
Characteristics of the study population according to gender at 10-year follow-up ($n = 58$) after a femoral neck fracture treated with closed reduction and internal fixation. Data presented as n (%).

	All patients$n = 58$	Men$n = 28$	Women$n = 30$	p-value
Mean age (SD)	58	66 (11.3)	67 (11.0)	0.67[a]
BMI mean (SD)[b]	24 (4)	24.5 (3.3)	22.7 (3.1)	0.07[a]
	n (%)	n (%)	n (%)	
Fracture type				
Non-displaced fracture	22 (38)	8 (29)	14 (47)	0.16[c]
Displaced fracture	36 (62)	20 (71)	16 (53)	
ASA				
1	20 (35)	13 (46)	7 (23)	0.03[c]
2	25 (43)	7 (25)	18 (60)	
3	13 (22)	8 (29)	5 (17)	
Smoking				
Yes	13 (22)	6 (21)	7 (23)	0.86[c]
No	45 (78)	22 (79)	23 (77)	
Major re-operation				
Yes	17 (29)	8 (29)	9 (30)	0.91[c]
No	41 (71)	20 (71)	21 (70)	

[a] Independent Samples Test,.
[b] missing 1,.
[c] Chi-square test.

was evaluated when possible otherwise the values from the lumbar spine were used. The results were expressed as both areal density (g/cm²) and as standard deviation units related either to the mean value of healthy young individuals, (T-score) or to the mean value of age- and sex-matched adults (Z-score) according to recommendation by the International Society of Clinical Densitometry [30]. Z -score < -2 standard deviation (SD) was considered as a low BMD [30]. A T-score > -1 SD was considered a normal BMD, osteopenia if T-score of -1 to -2.49 SD and osteoporosis if T-score ≤ -2.5 SD [31].

Patients were asked about history or on-going medical treatment for osteoporosis.

Surgical complications

Radiographics of the previously fractured hip were assessed as healed fracture and avascular necrosis was defined as segmental collapse, loss of sphere of the femoral head or subchondral fracture [32].

A major re-operation was defined as a hip replacement and a minor re-operation if only the screws were extracted.

Living condition, walking ability, smoking and ASA score

Living conditions were registered as independent (i.e. own home or block of serviced flats) or as institutionalized. Walking ability was recorded as walking outdoors, walking indoors or unable to walk. Use of walking aids or not was recorded. The ASA score [15] was assessed at the 10-year follow-up and were divided into 5 scores (ASA 1–5) depending on the physical status of the patient. Current smokers were coded as smokers.

All patients were treated according to identical study protocols. All assessments were carried out by physicians involved in this research project.

Statistics

Statistical calculations were performed using SPSS version 26 for Windows (IBM, SPSS Statistics). Mean, (SD), and percentage were used for descriptive purposes. Pearson's chi-square test was used for testing differences in contingency tables. Student T-Test and paired-sample T-test were used in continuous variables. A p-value of less than 0.05 was considered statistically significant in all analyses.

Ethical considerations

The study was conducted according to the Helsinki Declaration [33] The local Ethics Committee (Dnr. 2001–427, Dnr. 2013–602–32) approved the protocols. STROBE guidelines were used when reporting of the study [34]. The study was funded by grants provided by Region Stockholm (ALF project).

Results

General characteristics

Baseline characteristics are displayed in Table 1. From the primary cohort of 92 patients from three university hospitals, two patients were de-registered from the public record, 22 patients were deceased and 10 patients declined participation or were not located. A total of 58 patients participated in the 10-year follow-up (Fig. 1). The average age at 10-years follow-up was 67 years (range 32–80 years, 52% women). All but one still lived independently.

Only seven patients used walking aids in form of crutches or a walker. There were 22% ($n = 13$) current smokers. A total of 35% ($n = 20$) were classified as ASA grade 1, 43% ($n = 25$) grade 2 and 22% ($n = 13$) grade 3.

Analysis of baseline data of the 10 patients who did not want to participate revealed that the mean age at time of fracture was 59 years compared to 55 years for the included patients ($p = 0.096$). No significant differences were seen between "drop-outs" and participants in the FFMI ($p = 0.26$), BMI ($p = 0.23$), displaced fracture or not ($p = 0.92$), BMD ($p = 0.134$) and ASA ($p = 0.613$) at the time of fracture (data not shown).

Performance based functional tests and muscle strength

5TSTS showed that 45% ($n = 26$) managed to do the test within 15 s, 45% ($n = 26$) needed longer time and 10% ($n = 6$) could not perform the test at all. Age above 70 years was a significant factor associated with poor performance (Table 2).

The 4-m walking speed test showed an average speed of 1,2 m/s with a range of 0.47–2.2 m/s. Walking speed of $\geq$ 0.9 m/s was found in 76% ($n = 44$) of the patients (mean age 67 years), whereas 14% ($n = 8$) displayed a low walking speed ($\leq$ 0.8 m/s), and 10% ($n = 6$) could not perform the test. Table 2 indicates that mainly high age and need of walking aids were linked to reduced gait speed.

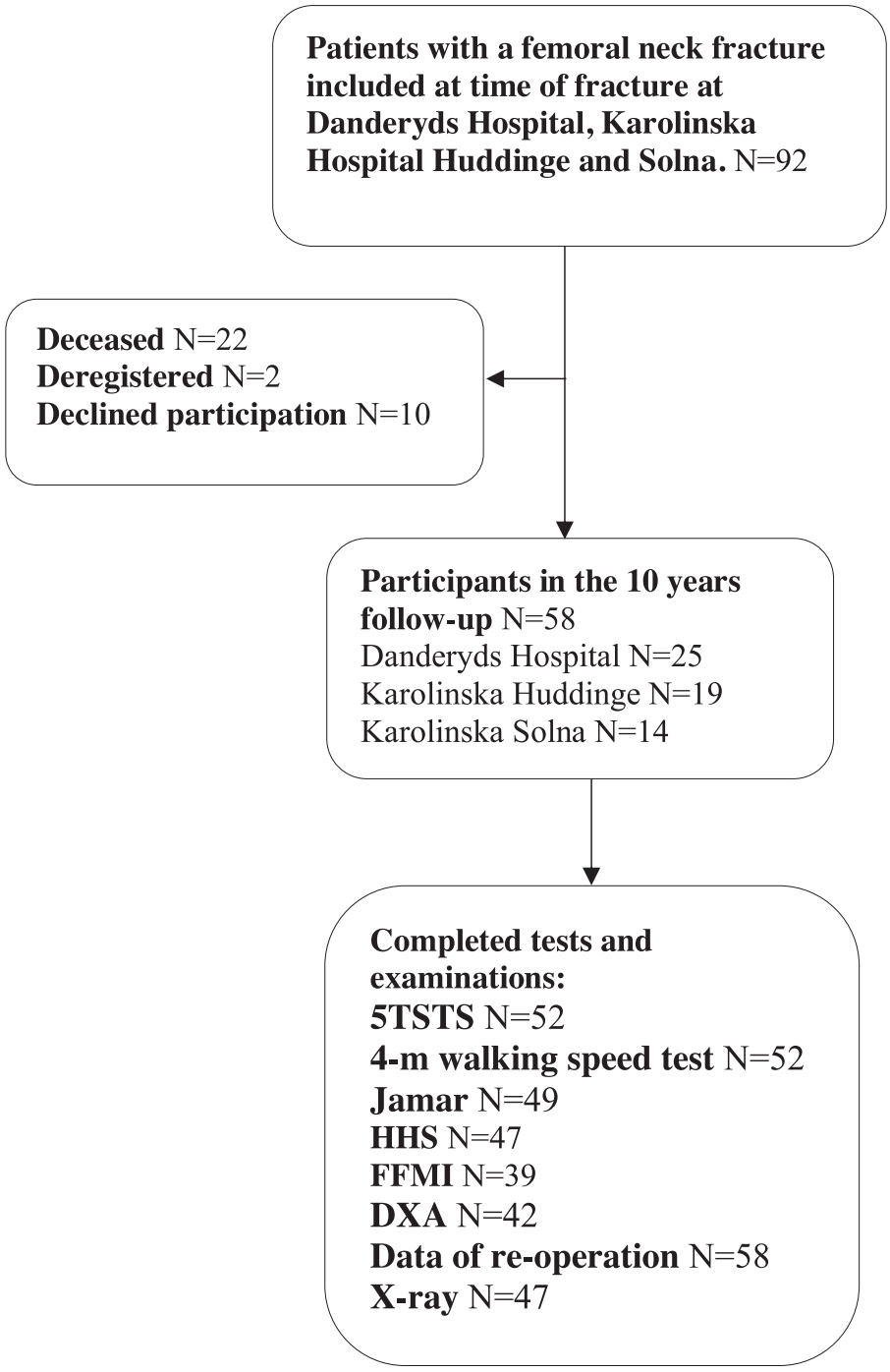

Fig. 1. A flowchart of the numbers of patients with completed tests at 10-year follow-up.

HGS was normal in a majority of both men (82%) and women (64%). There was no statistical difference in HGS between gender ($p = 0.22$), fracture type ($p = 0.92$) and those who had undergone a major re-operation or not ($p = 0.98$) (data not shown). However, older age as a continuous variable was significantly associated with poor hand grip performance ($p = 0.02$).

Body composition and occurrence of sarcopenia

At the 10-year follow-up, mean FFMI for men was 18.2 (SD 1.3) and for women 14.8 (SD 1.2). Low FFMI values (<17 and <15 kg/m^2 in men and women respectively) were seen in 17% ($n = 3$) of the men and 57% ($n = 12$) in women; $p = 0.02$ between gender (Fig. 2). Patients that had undergone a major re-operation had a significant lower FFMI compared to patients with no major re-operation ($p = 0.01$), (Fig. 2). There were no differences between patients with a displaced and non-displaced FNF ($p = 0.31$), (Fig. 2).

Finally, sarcopenia defined as the combined reductions in muscle strength (by HGS or 5STST) and low FFMI was observed in 17% of the men and in 38% of the women. A paired sample *t*-test comparing FFMI at base-line and at the 10-years follow-up, did not show a significant change ($p = 0.66$) over time. At baseline the FFMI was 18.0 (SD 1.3) for men and 14.9 (0.9) for women.

The mean BMI at the follow-up for women was 22.7 (SD 3.1) and for men 24.5 (SD 3.3); $p = 0.07$ between genders. There was no change in BMI over the 10-year observation period ($p = 0.18$).

Table 2
Results of Five times sit and stand test and 4-m walking test divided into gender, age group, re-operation, type of fracture, ASA-class and use of walking aids in patients with a femoral neck fracture at 10-year follow-up, $n = 52$.

Variable	Number Total (n)	Sit and stand test <15 s% (n)	Sit and stand test >15 s% (n)	p-value [1]	Gait speed ≥0.9 m/s% (n)	Gait speed ≤0.8 m/s% (n)	p-value [1]
Sex							
Male	27	44 (12)	56 (15)	0.185	85 (23)	15 (4)	0.260
Female	25	56 (14)	44 (11)		84 (21)	16 (4)	
Age							
30–69 years	23	78 (18)	22 (5)	0.001	100 (23)	0 (0)	0.005
70–80 years	29	28 (8)	72 (21)		72 (21)	28 (8)	
Surgery							
No or minor	37	49 (18)	51 (19)	0.930	89 (33)	11 (4)	0.351
Major	15	53 (8)	47 (7)		73 (11)	27 (4)	
Fracture							
Non-displ.	18	56 (10)	44 (8)	0.509	78 (14)	22 (4)	0.608
Displaced	34	47 (16)	53 (18)		88 (30)	12 (4)	
ASA							
1–2	47	51 (24)	49 (23)	0.780	87 (41)	13 (6)	0.259
3–4	5	40 (2)	60 (3)		60 (3)	40 (2)	
Walking aids							
None/cane	45	58 (26)	42 (19) 100 (7)	0.002	87 (41)	13 (6)	0.001
Walker/ two crutches	7	0 (0)			60 (3)	40 (2)	

[1] T-test.

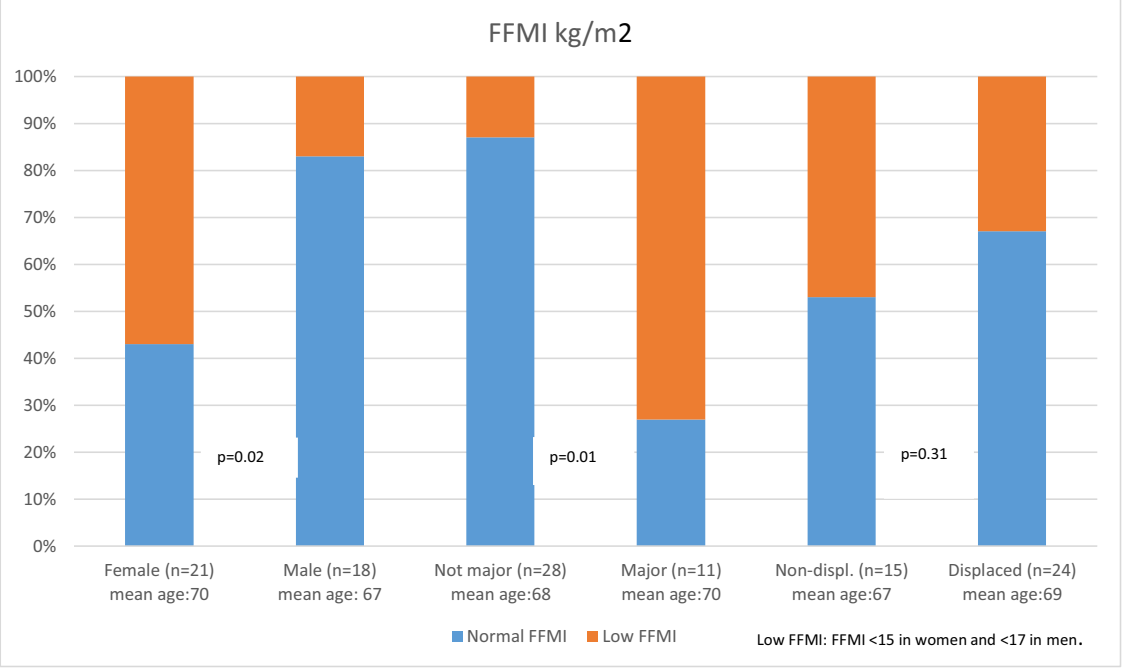

Fig. 2. Fat Free Mass Index (FFMI) presented as normal or low in% between gender, major re-operation or not and fracture type in patients with a previous femoral neck fracture 10 years ago treated with closed reduction and internal fixation. A value < 15 in women or < 17 in men are considered low and indicates sarcopenia.

Bone mineral density

The BMD was measured at the contralateral femoral neck in 34 patients and at the lumbar vertebrae in eight patients due to a hip-replacement in the contralateral hip. The mean BMD (gm/cm^2) for men was 0.697 (SD 0.08) and for women 0.682 (SD 0.08), ($p = 0.62$). The corresponding mean BMD (gm/cm^2) for the same patients at the time of fracture was higher for men and women; 0.772 (SD 0.112) and 0.758 (SD 0.105) ($p<0.02$), respectively. A clear majority (86%) of the former young hip fracture patients displayed reduced BMD at the follow-up; i.e. osteopenia in 74% ($n = 27$) and 12% ($n = 5$) had osteoporosis (Table 3). The mean age among patients with normal BMD, osteopenia and osteoporosis was 64, 68 and 73 years respectively ($p = 0.097$). All patients with a low BMD had a history or on-going medical treatment for osteoporosis except for two patients with osteopenia.

Surgical complications, radiographic examination of the hip and hip function

Twenty-nine percent ($n = 17$) had a major re-operation (THR) and 34% ($n = 20$) had a minor re-operation (extraction of the screws) during the 10-year observation period. In patients with a displaced FNF, 34% ($n = 13$) had a major re-operation compared to 20% ($n = 4$) in those with a non-displaced FNF. A total of 22% ($n = 13$) had sustained another fracture during the 10 years after the FNF and 9% ($n = 5$) suffered a fracture in the contralateral hip.

Table 3
BMD at 10-years follow-up divided into normal, osteopenia and osteoporosis in patients with a femoral neck fracture, $n = 42$. The results are comparing gender, age, fracture type as well as BMD at the time of fracture.

BMD	Normal (T-score>1)	Osteopeni (T-score −1 to −2.49)	Osteoporosis (T-score≤2.5)	p-value [1]
All patients% (n)	14 (10)	74 (27)	12 (5)	<0.001
Sex% (n)				
Women	9 (2)	70 (16)	21 (5)	0.01
Men	42 (8)	58 (11)	0 (0)	
Mean age	64	68	73	0.097
Type of fracture% (n)				
Non-displaced	12 (2)	76 (12)	12 (2)	0.395
Displaced	31 (8)	58 (15)	11 (3)	
Time of fracture% (n) [2]	10 (5)	50 (21)	40 (12)	0.006

[1] Chi-square test.
[2] Missing 4.

Table 4
Postoperative hip function according to Harris Hip Score in patients younger than 70 years with a femoral neck fracture at 4, 12 and 24-month and at 10-year follow-up, $n = 47$. A value between 80 and 100 are considered excellent, 70–80 good and <70 a poor function.

Harris Hip Score total score	4 months [a]	12 months	24 months [b]	10 years
Mean (SD)	81.3 (19.2)	85.7 (18.4)	88.7 (15.8)	88.3 (15.2)
p-value [c]	0.09	0.13	0.71	–
All fractures% (n)				
Poor function <70	22 (10)	18 (8)	33 (9)	15 (7)
Good function 70–80	11 (5)	9 (4)	11 (3)	13 (6)
Excellent function >80	67 (31)	73 (32)	56 (15)	72 (34)
Non- displaced fractures				
Poor function <70	5 (1)	17 (3)	17 (3)	10 (2)
Good function 70–80	11 (2)	0 (0)	6 (1)	16 (3)
Excellent function >80	84 (16)	83 (15)	78 (14)	74 (14)
Displaced fractures				
Poor function <70	33 (9)	19 (5)	11 (3)	18 (5)
Good function 70–80	11 (3)	16 (4)	0 (0)	11 (3)
Excellent function >80	56 (15)	65 (17)	89 (24)	71 (20)

Data missing:.
[a] n=1,.
[b] $n = 2$.
[c] Paired sample T-Test, data compared to 10-year follow-up.

The radiographic examination of the previously fractured hip showed a healed fracture in 60% ($n = 28$), AVN in four patients and osteoarthritis in one patient.

HHS showed good or excellent function in 85% of the patients (Table 4). The mean value for HHS was 86.0 (SD 18.2) for men and 90.5 (SD 11.5) for women ($p = 0.330$). For patients who had undergone a major re-operation, 67% showed a good or excellent function compared to 93% who had a minor or no re-operation ($p = 0.125$).

The HHS at the 10-year follow-up did not differ from that of the 2-year follow-up ($p = 0.711$) (Table 4).

Discussion

The reported findings indicate that a majority of these younger patients that sustained a FNF ten years earlier had a normal muscle strength and hip function. A third of the patients had undergone a major re-operation. Although a majority of all included patients did not display osteoporosis or sarcopenia, still a significant number had reduced BMD and muscle functionality.

The results of 5TSTS indicate that close to half of the patients had a reduced lower extremity strength, with potential implications for mobility and general functionality. Previous studies report factors such as age, balance, sensorimotor measures and weight play important roles in the performance of this test [23]. To our knowledge, no previous studies have investigated 5TSTS in younger patients 10 years after a FNF. Whitney et al. [21] concluded that 5TSTS is capable of identifying people with balance disorders especially in those younger than 60 years of age. Somewhat in contrast to the frequent impairment of chair-stand capacity our results show that 85% had a normal 4-m walking test. In line with some previous studies [26,27], older age and reliance on walking aids in our patients were linked to slow gait speed, rather than factors related to previous trauma.

Although the majority of the patients in our study performed well in HGS, up to one third displayed low HGS at the 10-year follow-up. As expected the strength declined with increasing age. More than half of the women displayed low FFMI, which was also the case for patients who had undergone a major re-operation. Still, the mean FFMI was similar 10 years after the hip fracture compared to the values at the time of inclusion, which may indicate that a FNF in this group of patients does not affect the FFMI. According to a European reference population [29] the FFMI were similar with those found in the present study except for men with overweigh (BMI 25–29.9) who had lower values of FFMI in our study. Sarcopenia, defined as a combination of reduced strength and reduced muscle mass/FFMI, was observed in up to one third of the study population. This finding is important, since the occurrence of sarcopenia and reduced chair-stand capacity may have implications for the management of activities of daily living and the risk of falls.

The BMI in our study did not change significantly between inclusion and follow-up. When comparing BMI at the follow-up with an age and sex matched reference group, our subjects showed a slightly lower BMI [35].

According to HHS the majority had a good or excellent hip function 10 years after the fracture, i.e., similar to the HHS score at the 24-month follow-up in the same cohort [9]. In a 12-month follow-up study of 153 patients with FNF, Frihagen et al. [36] found a HHS that was significantly lower if re-operated. Their follow-up was much shorter and included older patients which might explain their lower values of HHS after a re-operation.

BMD at the 10-years follow-up was as expected significantly lower when compared to baseline values. The BMD levels in this 10-year follow-up were similar to those reported in more than 7000 US inhabitants [37], where results were documented according to sex, age and ethnicity (non-Hispanic white). The majority of our patients had periods of treatment for osteoporosis, contrary to other studies showing less medical treatments for osteoporosis after a hip fracture [38]. A possible reason for our high level of osteoporosis treatment is that patients with osteopenia or osteoporosis at the time of inclusion in our study were referred to their GP or endocrinologist for further osteoporosis assessment and treatment according to existing guidelines.

Studies on patients at old age sustaining a displaced FNF have shown a re-operation rate of 35–47% [39,40], that are somewhat higher than in the present study. The lower re-operation rate in our study may reinforce the surgical guidelines we used for younger patients with FNF, regardless if non-displaced or not, to be treated with CRIF.

Some of the limitations and strengths of this study should be noticed. To our knowledge, no previous study has investigated functional outcome for the younger group of patients with a FNF. The patients who were available for a follow-up after 10 years may not be representative for the whole study group. Another weakness is that some of the included patients did not participate in all examinations. A strength of the present study is the long-term follow-up after a FNF in younger patients. Moreover, we find the design with combined performance and body composition measurements important, since it allows for assessment of sarcopenia, which is an emerging condition with great relevance for patients with hip fractures.

Conclusion

The majority of patients less than 70 years of age with a FNF treated with CRIF had a normal muscle strength and self-assessed function 10 years after the fracture. However, one in ten had osteoporosis, close to half were limited in their chair rising capacity, and up to one third were sarcopenic. The last findings indicate a challenge for the health care system to encourage younger hip fracture patients to do regular muscle preserving resistance training, especially those patients that had undergone a major re-operation and women. Further studies are needed to assure whether such training may have any beneficial effect.

Declaration of Competing Interest

The authors of this article certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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