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Immediate Full Weight-Bearing Versus Partial Weight-Bearing After Plate Fixation of Distal Femur Fractures in Elderly Patients. A Randomized Controlled Trial

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Abstract

Introduction: After surgery for distal femur fractures in elderly patients, weight-bearing is commonly restricted. Immediate non-restrictive weight-bearing might have beneficial effects. There are no randomized studies on the topic. The purpose of this study was to compare the functional outcome between immediate full weight-bearing (FWB) as tolerated and partial weight-bearing (PWB) during the first 8 weeks following plate fixation of distal femur fractures in elderly patients. **Methods:** Patients aged 65 years or older with distal femur fractures of AO/OTA types 33 A2, A3, B1, B2, C1, and C2 were included. Exclusion criteria were impaired cognitive function, concomitant injuries, or inability to follow the postoperative regimen. Internal fixation was achieved with an anatomical lateral distal femur plate applied as a strictly bridge-plating construct. The primary outcome measure was the function index of the short musculoskeletal functional assessment (SMFA) after 52 weeks from injury. **Results:** Thirty-two patients were randomized to FWB (n = 11) or PWB (n = 21). After 16 and 52 weeks, there were no differences in the mean SMFA function index between FWB and PWB (36 vs 43, $P = .42$ and 52 vs 40, $P = .18$, respectively) nor in the mean EuroQol 5-dimension index or range of motion (ROM). Overall, the SMFA function index was higher at 52 weeks compared with before injury (44 vs 30, $P = .001$) as was the mean bothersome index (37 vs 21, $P = .011$). There was no clear difference in the occurrence of adverse events between the treatment groups. **Conclusions:** There were no differences in functional outcome, adverse events, or ROM between immediate FWB and PWB following plate fixation for a distal femur fracture in elderly patients. A distal femur fracture has a negative effect on the functional status of elderly patients that persists at least up to 1 year following injury.

Keywords

distal femur fracture, geriatric trauma, weight-bearing, plate fixation, bridge-plating, functional outcome, rehabilitation

Introduction

The incidence of distal femur fractures is highest amongst the elderly.[1] Operative treatment is generally preferred over non-operative treatment[2] with plate fixation being a commonly used technique.[3-5] There is no consensus on the most appropriate regimen for postoperative weight-bearing. Restricted weight-bearing is commonly recommended, presumably as it is thought to decrease the risk of treatment failures, but this assumption has not yet been

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proven.[6] According to a systematic review and meta-analysis by Koso et al.,[7] the risk of revision following operative treatment of distal femur fractures was 6.4% for delayed and nonunion, and 3.6% for implant failure. Meanwhile, failure rates, in terms of nonunion or mechanical failures, of 5–7% have been reported with non-restrictive weight-bearing.[8-10] The risk of nonunion and mechanical failure has been suggested to decline with increased age.[4,11,12] When considering the optimal postoperative weight-bearing regimen for elderly patients, the risk of nonunion and mechanical failure has to be weighed against the potentially detrimental effects of immobilization. Elderly patients with distal femur fractures are frail, as emphasized by their high 1-year mortality rate[13] and restricted weight-bearing might increase mortality and harm bone healing and post-rehabilitation mobility.[14-17] Elderly patients often cannot restrict weight-bearing consistently.[18-21] It is, therefore, not clear that restricting weight-bearing is the most suitable postoperative rehabilitation strategy for elderly patients following a distal femur fracture. There has in recent years been a growing interest for less restrictive weight-bearing[22,23] but randomized controlled trials (RCTs) comparing non-restrictive and restrictive weight-bearing strategies for distal femur fractures in elderly patients have not been published.

The purpose of this study was to compare the functional outcome between immediate full weight-bearing (FWB) and partial weight-bearing (PWB) during the first 8 weeks postoperatively in elderly patients treated with strict bridge-plating according to a standardized protocol.

Material and Methods

Trial Design and Eligibility Criteria

This study was a single-center, parallel, two-arm, RCT conducted at the Sahlgrenska University Hospital, Gothenburg, Sweden. The inclusion criteria were a traumatic fracture of the distal part of the femur of AO/OTA types A2, A3, B1, B2, C1, and C2[24] and age 65 years or older. Exclusion criteria were concurrent injury or any pre-existing condition that could considerably affect rehabilitation, preinjury inability to ambulate independently with or without walking aids (crutches or walker), inability to communicate in the Swedish language, severe cognitive impairment (6 points or fewer) according to the Short Portable Mental Status Questionnaire[25], and open fractures of types II and III according to the Gustilo–Andersson classification.[26]

Surgery

Surgery was carried out within 72 hours after admission. All patients underwent surgery according to a standardized protocol based on pre-existing routine. Procedures were done by 1 of 7 consultant orthopedic trauma surgeons. The written protocol was made readily available to the involved surgeons who were also briefed on its content. The surgical protocol included positioning the patient on a traction table and reducing the fracture using closed techniques such as traction, with the fracture dorsally supported by a femur-support (Figure 1). The limited skin incision could be extended to allow additional open reduction when necessary. A stainless-steel LCP® Distal Femur Plate (Synthes™, Oberdorf, Switzerland) was introduced under the fascia lata using a minimally invasive technique. A 13- or 15-hole plate was used depending on the length of the femur (Figure 2). The plate was fixed to bone with locking screws. Distally 5 bi-cortical screws were used. Proximally 4 screws were inserted through stab incisions, the most proximal of these was mono-cortical but the remaining screws were bi-cortical. Only a strictly bridge-plating construct was allowed, no screws or cerclage wires were used across the fracture site. A biplanar image intensifier was used to verify adequate fracture reduction and hardware positioning.

Intervention: Full or Partial Weight-Bearing

Patients were randomized to either immediate FWB or PWB for the first 8 weeks postoperatively. The patients in both intervention groups received physiotherapy according to routine, including exercises that could be carried out in bed or while standing. They received thorough instructions from a physiotherapist on how to follow the allocated intervention. In the PWB group, weight-bearing was set to approximately 30% of body weight. Using a bathroom scale together with real-time visual feedback about weight-bearing, the physiotherapist trained the patient during the hospital stay. In the FWB group, patients could directly bear weight as tolerated. Patients in both groups could use whatever walking aids they needed postoperatively.

Figure 1. The patient in the supine position on a traction table. The arrow indicates the femur-supporting device.

Figure 2. A long spiral fracture of the distal femur fixed with a 15-hole plate. The osteosynthesis is done according to a strictly bridge-plating concept which results in a long working length. The image is digitally edited by merging 2 x-ray images.

Assessment of Outcome

Patients were followed up at 8, 16, and 52 weeks. The primary outcome measure was the function index of the short musculoskeletal functional assessment (SMFA).[27,28] The SMFA is a self-reported instrument which has been found to be valid for assessing the impact of musculoskeletal conditions on functional status.[29] The SMFA is composed of 2 indices: the bothersome index and function index. The latter has 4 categories: daily activities, emotional status, arm and hand function, and mobility. The range runs from 0 to 100 in each category and a higher score represents a greater impairment. Secondary outcome measures were the categories of the SMFA and the bothersome index, pain assessed in mm on a visual analog scale (VAS), ROM of the knee in degrees assessed with a goniometer, and the three-level EuroQol 5-dimension (EQ-5D) instrument.[30] The EQ-5D index was calculated as described by Dolan.[31] Preinjury patient-reported outcome was captured using the recall method referring to patients' functional status during the last 7 days prior to the injury. Preinjury function was also assessed by the Function Recovery Score[32] and a basic three-level classification regarding general medical health and social situation. ROM was assessed by the first author who was not blinded to treatment allocation. The "time-up-go" (TUG) test at 16 weeks[33] was conducted by an experienced senior physiotherapist who was blinded to treatment allocation.

Sample Size

An estimate of the minimal important difference was not available for the SMFA function index before initiating the study.[29] A *SD* of 15 was considered reasonable.[34] A group size of 35 patients in each group was aimed for and would detect a 10-point difference with 80% power and alpha set at .05.

Randomization

Patients were randomized immediately after surgery. This option was chosen since randomizing applied to the postoperative treatment selection. Randomization prior to surgery would have entailed a risk of the surgical procedure being adapted to the allocated treatment group.

Statistical Methods

Analysis was performed in SPSS® Statistics version 26 (IBM®, Armonk, NY, USA). Continuous data are presented as mean and *SD*. For comparisons between groups, an independent samples *t*-test was used for continuous variables and

Fisher's exact test for categorical variables. For comparisons between different timepoints, a paired samples *t*-test was used. Statistical significance was set at $P > .05$.

Clinical Trial Registry

This study was entered (registration number 115861) on December 4, 2012, in the national clinical trial registry; The Healthcare Committee, Region Västra Götaland, Sweden.

Results

Between January 2013 and June 2016, 32 patients were enrolled in this study. Eleven patients were randomized to FWB and 21 patients to PWB, (Figure 3). Two patients in the PWB group died and 1 was lost to follow-up prior to follow-up at 8 weeks and were excluded from further analysis. There were thus 11 patients in the FWB group and 18 patients in the PWB group with data available from follow-ups who were included in the analysis.

There were no statistically significant differences in demographic and clinical characteristics between the treatment groups except that the mean duration of surgery in minutes was shorter in the FWB group compared to the PWB group (Table 1).

Overall, the distribution of AO/OTA fracture types was similar in both groups (Table 2). Four patients in each group had extra-articular type A fracture that extended substantially into the shaft. The occurrence of peri-implant fractures was high, 64% in the FWB group and 72% in the PWB group (Table 3).

There were no statistically significant differences between the treatment groups in the means of the SMFA indices, EQ-5D index (Table 4), or ROM (Table 5) at any time point. When analyzing patients from both treatment groups with available data (n = 18) together, SMFA function and bothersome indices were higher at 1-year follow-up than before the injury (44 vs 30, $P = .001$ and 37 vs 21, $P = .011$, respectively).

At the 1-year follow-up, there were no statistically significant differences between the treatment groups in mean pain (VAS) when walking (Figure 4) or at rest (Figure 5). The mean VAS scores were highest postoperatively but gradually declined over time in both treatment groups.

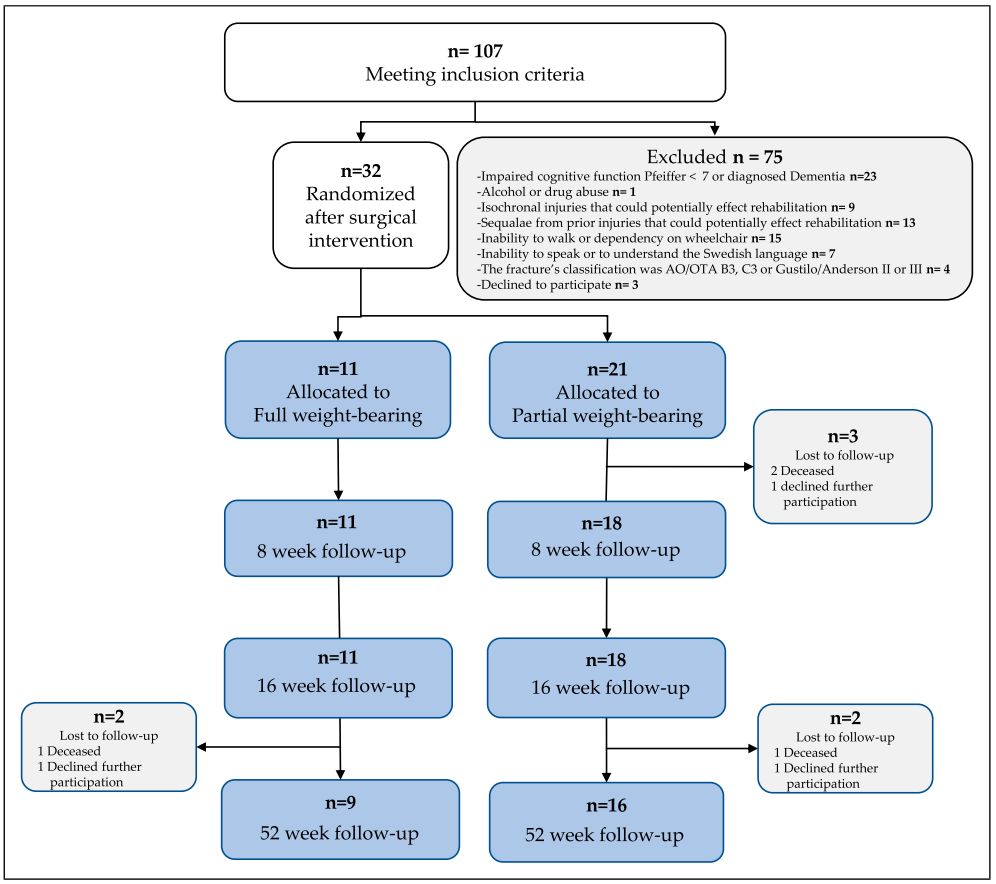

Figure 3. Flowchart showing the pathway of the patients through the study.

Table 1. Demographic and Treatment-Related Data.

	FWB (n =11)	PWB (n = 18)	*P*-value
Age in years, mean (*SD*)	79.2 (9)	81.3 (8)	.55[a]
Sex, n (%)			1.0[b]
Women	10 (91)	15 (83)	
BMI, mean (*SD*)	27.6 (4.6)	25.2 (4.2)	.15[a]
ASA class, n (%)			.64[b]
ASA I	2 (18)	1 (6)	
ASA II	5 (45)	8 (44)	
ASA III	4 (36)	9 (50)	
FRS, n (%)			.48[b]
90–100%	9 (82)	13 (72)	
80–89%	2 (18)	1 (6)	
70–79%	0 (0)	2 (11)	
Missing		2 (11)	
Medical general condition, n (%)			1.0[b]
A; No other injury or illness	3 (27)	4 (22)	
B; Isochronal injury or illness, not affecting rehabilitation	4 (36)	6 (33)	
C; Isochondral injury or illness, possibly affecting rehabilitation	4 (36)	8 (44)	
Social situation, n (%)			1.0[b]
Con with relatives, n (%)			
A; More than once a week	10 (91)	15 (83)	
B; More than once a month	1 (9)	3 (17)	
C; Less that once a month	0 (0)	0 (0)	
Surgery, mean (*SD*)			
Hours from injury to surgery	34 (13)	37 (21)	.61[a]
Duration of surgery in minutes	83 (21)	104 (22)	.022[a]
Blood loss in ml	268 (184)	275 (132)	.90[a]

ASA, American Society of Anesthesiologists Classification; BMI, Body mass index; FWB, Full Weight-Bearing; FRS, Function Recovery Scale; PWB, Partial Weight-Bearing.
[a]Independent Sample *t*-test.
[b]Fischer's exact test.

Table 2. AO/OTA Fracture Classification.

	FWB (n)	PWB (n)
AO/OTA fracture type		
A, Extra-articular	5	7
B, Partial articular	1	0
C, Complete articular	1	3
V.3 B 1, Bed of or around stable implant TKR	2	4
V.3 C, Proximal to the implant and cement mantle TKR	1	0
IV.3 C a, Distal to a THR	0	1
V.3 D, Between THR and TKR, close to the knee	1	3

AO/OTA, Arbeitsgemeinschaft für Osteosynthesefragen/Orthopaedic Trauma Association; TKR, Total Knee Replacement; THR, Total Hip Replacement.

Results of the TUG test were available for 7 patients in each treatment group at 16 weeks of follow-up. Patients in the FWB group were somewhat faster compared to the PWB group (20.3 vs 25.4 seconds, respectively), although the difference was not statistically significant, $P = .34$. There was no difference in the mean length of hospital stay between the FWB group (14.6 days, *SD* 6.6) and the PWB group (14.3 days, *SD* 5.7), $P = .87$. However, all the patients in the FWB were discharged directly to their homes, whereas 3 patients in the PWB group were discharged to a permanent nursing home.

Adverse Events

There were few adverse events in overall terms and there was no clear difference in their pattern between the treatment groups (Table 6). There was one death in the FWB group and 3 in the PWB group. One patient in the

Table 3. Distribution of Combinations of Peri-Implant Fractures.

	FWB	PWB
	(n)	(n)
Peri-implant fractures		
Single implant		
THR	0	3
TKR	2	4
Hip ORIF	3	3
2 implants		
THR and TKR	1	3
TKR and Hip ORIF	1	0

FWB, Full Weight-Bearing; PWB, Partial Weight-Bearing; THR, Total Hip Replacement; TKR, Total Knee Replacement; ORIF, Open reduction and internal fixation.

PWB group died of pulmonary embolism while still in hospital, the other deaths occurred at 21, 182, and 364 days after surgery, none of them were directly related to the femur fracture or its treatment.

Discussion

The main finding of this randomized study is that, for elderly patients treated with plate fixation for a traumatic distal femur fracture, there was no difference in patient-reported outcome between the patients who were allowed immediate full weight-bearing and those who were assigned PWB during the initial 8 weeks after surgery.

To the best of our knowledge, no previous randomized studies compare different weight-bearing strategies for distal femur fractures. The results of the current study are, however, consistent with previous non-randomized

Table 4. Results of PROMs (EQ-5D and SMFA) at different time points (Preinjury, 8 weeks, 16 weeks and 52 weeks).

	Preinjury			8 weeks			16 weeks			52 weeks		
	FWB	PWB		FWB	PWB		FWB	PWB		FWB	PWB	
	(n = 10)	(n = 18)	*P*-value	(n = 11)	(n = 12)	*P*-value	(n = 9)	(n = 15)	*P*-value	(n = 7)	(n = 12)	*P*-value
EQ-5D, mean (*SD*)												
EQ-5D index	.72 (.30)	.63 (.32)	.64	.55 (.23)	.51 (.28)	.70	.59 (.29)	.54 (.23)	.66	.61 (.20)	.64 (.20)	.72
EQ-5D VAS	74 (21)	78 (15)	.45	53 (23)	52 (24)	.92	71 (20)	56 (23)	.15	54 (16)	65 (21)	.32
SMFA, mean (*SD*)												
Function index	**29 (23)**	**35 (21)**	**.45**	**45 (17)**	**47 (17)**	**.78**	**36 (23)**	**43 (20)**	**.42**	**52 (19)**	**40 (16)**	**.18**
Daily activity	37 (33)	44 (28)	.57	59 (23)	70 (24)	.30	47 (28)	58 (30)	.37	62 (28)	51 (26)	.42
Emotional status	27 (24)	31 (18)	.58	36 (18)	43 (15)	.38	31 (23)	39 (18)	.34	46 (11)	41 (19)	.59
Arm and hand function	19 (23)	24 (25)	.64	27 (26)	20 (20)	.51	19 (27)	19 (22)	.99	37 (29)	19 (17)	.11
Mobility	30 (20)	37 (20)	.31	51 (16)	50 (21)	.85	41 (20)	50 (22)	.32	50 (25)	44 (18)	.54
Bothersome index	**19 (21)**	**28 (29)**	**.31**	**38 (18)**	**41 (18)**	**.71**	**26 (21)**	**37 (22)**	**.23**	**41 (17)**	**35 (19)**	**.60**

EQ-5D, EuroQol 5-Dimensions; FWB, Full Weight-Bearing; PROMs, Patient reported outcome measures; PWB, Partial Weight-Bearing; SMFA, Short musculoskeletal function assessment; VAS, Visual analog scale.

Table 5. Range of Motion at 8, 16, and 52 weeks of Follow-Up.

	8 weeks			16 weeks			52 weeks		
	FWB (n = 11)	PWB (n = 17)	*P*-value	FWB (n = 10)	PWB (n = 16)	*P*-value	FWB (n = 9)	PWB (n = 13)	*P*-value
Range of knee motion in degrees, median (*SD*)									
Active flexion	105 (14)	100 (24)	.55	110 (10)	106 (21)	.66	110 (18)	110 (19)	.96
Active extension	0 (3)	0 (5)	.37	2 (3)	3 (5)	.32	1 (2)	2 (6)	.49

FWB, Full Weight-Bearing; PWB, Partial Weight-Bearing.

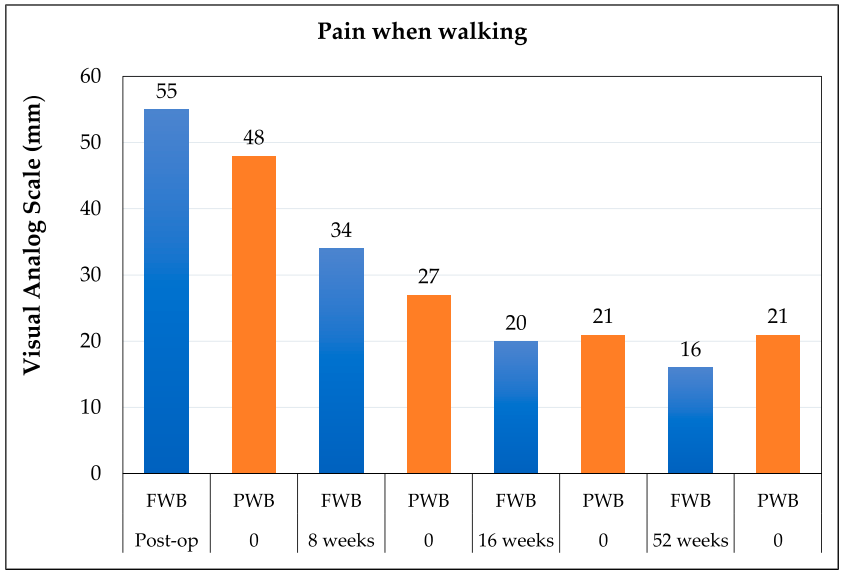

Figure 4. Reported pain when walking, measured by Visual Analog Scale (VAS) during follow-up. FWB, Full Weight-Bearing; PWB, Partial Weight-Bearing.

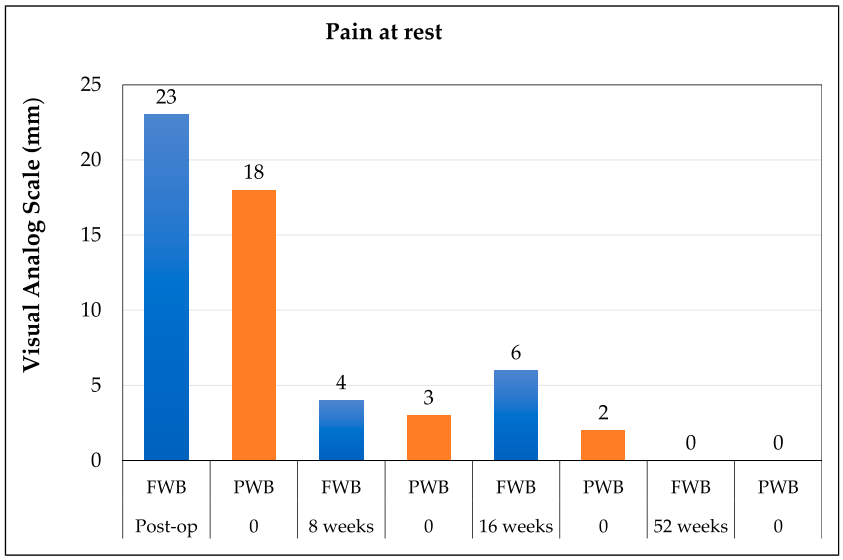

Figure 5. Reported pain while resting, measured by Visual Analog Scale (VAS) during follow-up. FWB, Full Weight-Bearing; PWB, Partial Weight-Bearing.

studies which have not demonstrated a clear advantage of any weight-bearing strategy in terms of function[35,36] or the occurrence of complications.[8-(10)]- PWB was the standard treatment locally when the study was started and was therefore chosen as the treatment with which to compare FWB. The weight-bearing strategies reported by previous studies vary considerably in the loading allowed but are collectively referred to here as those with restrictive or non-restrictive weight-bearing.

Two non-randomized comparative studies by Bruggers et al.[35] and Lieder et al.[36] found no difference in the results of Patient Reported Outcomes (PRO) between non-restrictive and restrictive weight-bearing strategies, consistent with the results of the current study. Lieder et al. compared *weight-bearing as tolerated* (n = 56) and *touch-down weight-bearing* (n = 79) following internal fixation of patients 60 years and older with type A distal femur fractures. The degree of weight-bearing was at the discretion

Table 6. Patients With Adverse Advents.

	FWB (n)	PWB (n)	Treatment	Timepoint	Outcome
Adverse events requiring major reoperation					
Proximal screw breakage adjacent to THR	0	1	Revision of proximal fixation with LAP	4 months	Union
Deep infection	0	1	DAIR	2 months	Infection eradication and union
Delayed union, due to undetected atypical fracture	1	0	Initially non-operative treatment but ultimately addition of lag screws	14 months	Union
Adverse events requiring minor reoperation					
Independent new fracture of the lateral femur condyle, 1 week postoperatively	0	1	Screw removal distally	8 months	United distal femur fracture, poor knee function
Screw tip protruding through the medial cortex of the femur condyle	1	1	Exchange to shorter screws	2 and 5 months	Pain and discomfort subsided

DAIR Debridement Antibiotics Implant Retention; FWB, Full Weight-Bearing; LAP, Lateral Attachment Plate; PWB, Partial Weight-Bearing; THR, Total Hip Replacement.

of the surgeon. The presence of factors associated with an increased risk of failure, such as fracture comminution[37] and mal-reduction[38] might have affected group allocation which could explain the uneven distribution of fixation techniques between the treatment groups. In the weight-bearing as tolerated group, 50 of 56 were treated with an intramedullary nail but 46 of 79 in the touch-down weight-bearing group with a plate. However, Lieder et al. found no differences between the treatment groups in the mean Patient-Reported Outcomes Measurement Information System (PROMIS) scores, data which were collected by telephone.

Knee-specific PROMs might detect potential differences between weight-bearing strategies better than more generic instruments, such as the PROMIS or the SMFA used in the current study. Using the knee-specific Oxford knee score Bruggers et al. however, found no difference in mean scores at 6 weeks, 12 weeks, or 6 months between *weight-bearing as tolerated* (n = 11) and *protective/non-weight-bearing* (n = 35) in patients over 64 years of age treated with plate fixation. Again, treatment allocation was surgeon-based and potentially affected by risk factors for failure[37,39] since patients with diabetes were completely absent and patients with overweight underrepresented in the *weight-bearing as tolerated* group.

The mean scores of the SMFA function index were between 36 and 52 points after 4 and 12 months of follow-up in both treatment groups, indicating significant impairment. These values are comparable to a mean of 44 points on the SMFA function index reported by Shulman et al.,[40] based on patients aged 65 years or older treated with a plate or intramedullary nail for AO type B or C femur fractures after 2.1 years of follow-up. These values, like those in the current study, imply considerable impairment. In the current study, both SMFA function and bothersome indices indicated significantly worse function at 1-year follow-up than before the injury. These findings emphasize that sustaining a distal femur fracture often substantially affects the life of elderly patients.

The main concern with nonrestrictive weight-bearing is a potential increase in the risk of failure in terms of nonunion with or without implant breakage. In a systematic review and meta-analysis on distal femur fractures, Koso et al.,[7] reported an overall risk of revision for nonunion, delayed union, and mechanical failure of 10%. In another meta-analysis, Yoon et al.[41] estimated that approximately 5% of patients with distal femur fractures treated with locked compression plates or intramedullary nails develop nonunion. In the current study, there were few adverse events overall (Table 6), and no clear difference between FWB and PWB. This is consistent with 3 previous studies, which have found no increase in the occurrence of treatment failure for non-restrictive as compared to restrictive weight-bearing strategies (Table 7).[10,36] Furthermore, there is no clear difference between cohort studies using non-restrictive weight-bearing[8,9,42-44] and restrictive weight-bearing[45-48] after internal fixation of distal femoral fractures, and treatment failures occurring with both types of strategies (Table 8).

In addition to potentially affecting function, different weight-bearing strategies might have other implications although data concerning distal femur fractures specifically is limited. From other studies it is, however, known that loading has a positive effect on fracture healing,[17] and muscle disuse has been found to cause rapid muscle atrophy and potentially loss of functional health.[49,50] Studies on hip fractures have found that early weight-bearing decreases mortality[15,16] and the occurrence of complications such as pneumonia[51] and pressure ulcers[15] while

Table 7. Overview of Studies Comparing Restrictive and Non-restrictive Weight-Bearing Strategies for Distal Femur Fractures.

			Weight-bearing strategy (n)						Treatment (n)		AO classification (n)					
			Non-restrictive		Restrictive										Treatment failure	
First author	Year	Included in analysis (n)	As tolerated	Early	Touch- down	Protective/non	Non	Mean age (years)	Plate	RIMN	A	B	C	Follow-up (months)	Non-restrictive (n and %)	Restrictive (n and %)
Lieder et al. [36]	2021	135	56		79			76	52	83	135	0	0	21	6 11%	11 14%
Bruggers et al.[35]	2020	46	11			35		75	46		37	2	7	12	0	2 6%
Consigliere et al.[10]	2019	51		19			32	64	51		13	3	20	3	0	2 6%

AO, Arbeitsgemeinschaft für Osteosynthesefragen; RIMN, reamed intramedullary nail;

Table 8. Overview of results of cohort studies on distal femur fractures which specify type of weight-bearing strategy used.

First author	Year	Included in analysis (n)	Weight-bearing strategy (n)				Mean age (years)	Treatment (n)		AO classification (n)			Follow-up (months)	Treatment failures (n and %)	
			Non-restrictive	Restrictive											
			As tolerated	Partial	Touch- down	Non		Plate	RIMN	A	B	C			
Non-restrictive weight-bearing															
Poole et al.[8]	2017	127	107				73	127		107	4	16		4[b]	5%
Smith et al.[9]	2016	54[a]	54				74	54					12	4[c]	7%
Doshi et al.[42]	2013	24	24				73	24		20	1	3	15	0	
Kanakaris et al.[44]	2019	36	36				77	36					9	5	14%
Giddie et al.[43]	2015	54	54				81		54	54			4	0	
Restrictive weight-bearing															
Tank et al.[48]	2016	67				67	55	67		16	1	50	10	11	16%
Loosen et al.[46]	2019	50	3	19		28		50		40	4	8		0	
Khursheed et al.[45]	2015	25			25		67	25		25				0	
Patterson et al.[47]	2020	78				78	60	78		38	41		25	3	4%

AO, Arbeitsgemeinschaft für Osteosynthesefragen; RIMN, Reamed intramedullary nail.
[a]54 fractures in 52 patients.
[b]4 of 85 with available data.
[c]3 implant failures and 1 nonunion.

non-weight-bearing status compromises functional level.[52] It appears reasonable to infer that this also applies for distal femoral fractures[53] since, despite differences in biomechanics and treatment-related issues, patients with proximal femur fractures have demographics similar to those with distal femur fractures concerning age, co-morbidities, and risk of mortality.[54,55]

Summarizing the literature regarding the effect of weight-bearing on the outcome of distal femur fractures in elderly patients is difficult. This is in part due to the risk of bias and the limited number of patients in both the current and previous studies. Lieder et al. estimated that, based on their data, 574 patients would be required to detect a difference in the occurrence of major adverse events with a power of .8.[36] Interpretation of the literature would be facilitated by standardized weight-bearing protocols and consistent terminology. In addition, it would be useful if all studies on distal femur fractures would specify the weight-bearing strategy used, which is currently not the case.[12,56-59]

Based on available knowledge regarding the effects of restrictive and non-restrictive weight-bearing discussed in the preceding paragraphs, it seems reasonable to suggest non-restrictive weight-bearing for elderly patients with distal femur fractures. Non-restrictive weight-bearing might, however, not be appropriate for all patients. Therefore, patient factors, such as obesity and open fractures which have been associated with an increased risk of treatment failure,[11,39] need to be considered when choosing weight-bearing strategy. Drawing firm conclusions about the most appropriate weight-bearing strategy for elderly patients following distal femur fractures must be deferred until large trials comparing restrictive and non-restrictive weight-bearing are available.

Limitations

Including eligible patients and implementing the study proved to be more difficult than expected. Unfortunately, the treatment groups were of unequal size, attributable to treatment allocation being done with simple randomization. Based on the inclusion rate and interim results, it was clear that obtaining a sizable cohort of patients would not be possible to accomplish within a reasonable timeframe. The study was therefore terminated. Unfortunately, the rate of discontinuation of RCTs may be as high as 43% with slow recruitment being the most common reason for discontinuation.[60] There are, however, no previous RCTs available on the topic and the data can be used for future meta-analysis and planning of future trials. There were only 4 patients with complete articular fractures which needs to be considered when interpreting the results. The follow-up did not extend beyond 1 year, in part as the advanced age and co-morbidities in the study population make a longer follow-up difficult. In addition, it appears plausible that a potential difference in function would make itself known during the first year of follow-up.

Conclusion

In this RCT, no difference was detected in functional outcome between FWB as tolerated and PWB during the first 8 weeks postoperatively in patients aged 65 years or older, treated with plate fixation for distal femur fractures. Treatment failures were not overrepresented in the FWB group. These results are consistent with previous non-randomized studies. Both the SMFA function and bothersome indices indicated worse function at 52 weeks as compared to before the injury, emphasizing the lasting impact distal femur fractures can have on the life of elderly patients.

Declaration of Conflicting Interests

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Clinical Trial Registry

This study was entered (registration number 115861) on December 4, 2012, in the national clinical trial registry; The Healthcare Committee, Region Västra Götaland, Sweden.

Ethical Considerations

This study was approved by the Regional Ethical Review Board in Gothenburg (entry number 008-12). All patients provided written informed consent to participate in the study.

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